ANSI-ASQ National Accreditation Board

Date: May 19th, 2017

Attn: Chief of the Office of Engineering and Technology, U.S. Federal Communications Commission

Re: Test Laboratory Accreditation Body Recognition Request

1. Submission Request:

The ANSI-ASQ National Accreditation Board (ANAB) requests recognition and classification as a recognized accreditation body by the U.S. Federal Communications Commission (FCC) to accredit testing laboratories in non-MRA countries to conduct testing on products subject to the FCC Certification and Declaration of Conformity (DoC) approval procedures.

The following is provided in support of information requested FCC KDB publication 974614 D02 (Accreditation Body Recognition v01).

2. General Information:

a) ANAB contact information:

Natalia Larrimer
Specialist, Regulatory Affairs and Business Development
Email: nlarrimer@anab.org
Phone: 414-501-5445

b) General Information on ANAB:

The ANSI-ASQ National Accreditation Board (ANAB) was established more than 25 years ago and is jointly owned by the American National Standards Institute (ANSI) and the American Society for Quality (ASQ). ANAB is non-profit, non-governmental organization that provides accreditation services to public- and private-sector organizations for management systems certification bodies, laboratories, inspection bodies, reference material producers, and proficiency test providers. Under the ANSI brand, we accredit product certifiers and personnel certifiers and provides for accreditation of standard developers.

ANAB is currently recognized by the FCC as Test Firm Accreditation Body (TFAB) for laboratories located in the United States. In addition, ANAB is listed by the National Institute for Standards and Technology (NIST) as a qualified accreditation body to accredit EMC/Telecom testing laboratories. The ANSI brand is recognized to accredit telecommunication certification bodies (TCBs) under the FCC program and by NIST under the National Voluntary Conformity Assessment Evaluation program (NVCASE) program.

ANAB's mission is to be a leader in guiding the international development of accreditation processes that build confidence and value for stakeholders worldwide and providing high quality and reliable accreditation services with the most professional value-added services for customers and end users.

c) Scope of work for which recognition is requested:

ANAB is seeking recognition as a TFAB to accredit and designate testing laboratories located in non-MRA countries to the requirements of ISO/IEC 17025, and in accordance with the FCC KDB 974614 D02 Accreditation Body Requirements.

ANAB also is requesting recognition to accredit and designate testing laboratories in non-MRA countries to conduct testing on products subject to the FCC Certification and Declaration of Conformity (DoC) approval procedures for all Scopes of Accreditation identified in Appendix A, contained within KDB 974614 D01 Accredited Test Laboratory Program Roles and Responsibilities.

d) Countries in which ANAB request recognition to provide laboratory accreditations:

ANAB is requesting TFAB recognition to accredit laboratories in the following non-MRA countries:

- People's Republic of China - 19
- Indonesia - 0
- India - 3
- Philippines - 2 pending
- Russia - 5
- Switzerland - 4
- Thailand - 4 and 1 pending
- Ukraine - 0

The above numbers indicated the number of laboratories accredited or in process of accreditation in each of the countries. Currently none of these testing facilities are accredited under FCC requirements.

e) Authorizations by government in each country for which recognition is requested, to operate and perform accreditation services:

ANAB has been accrediting organizations globally since the start of its operations, with approximately 2,000 current accreditations in more than 50 different countries.

Accreditation is a global approach and ANAB is not aware of any issues with accessing facilities or any requirements for registration or licensing for the purpose of accreditation in any of the countries involved. To our knowledge, other U.S. accrediting bodies have been able to provide accreditation to testing facilities in all of the above-listed countries without any special registration or licensing requirements.

ANAB currently accredits laboratories in all but two of the countries where ANAB is requesting recognition.

- People's Republic of China - 19
- Indonesia - 0
- India - 3
- Philippines - 2 pending
- Russia - 5
- Switzerland - 4
- Thailand - 4 and 1 pending
- Ukraine - 0

f) Evidence of ability to perform assessments in each country that ANAB plans to accredit testing laboratories:

ANAB has experience with accrediting laboratories outside the United States. A full list of ANAB-accredited laboratories and locations is available at www.anab.org.

ANAB proposes only highly qualified and experienced personnel relative to the proposed scope of accreditation. Our personnel are experts in accreditation and technical areas of testing, including electrical. All assessors are required to have a university education in the science for which they audit, and most have more than 20 years of relevant industry experience.

If additional assessors are needed for the operation, ANAB has proven methods for timely recruitment of high quality candidates. ANAB's high standards for the initial pre-qualification criteria allow for an initial training period of approximately two-weeks. Upon successful completion of initial training, a candidate is assigned as a member of an assessment team. All assessors initially operate as team members to allow access to and oversight by an experienced team leader. In addition, all assessors are subject to program-specific monitoring, training, and official evaluations of their performance. ANAB has established processes to deal with situations in which an assessor does not perform in accordance with ANAB expectations and/or any requirements of the program owner.

ANAB operations and its laboratory accreditation process are accepted as conforming to the requirements of ISO/IEC 17011 and additional international requirements by ILAC, APLAC, and IAAC. In many respects ANAB goes above and beyond these requirements.

To ensure uniformity and impartiality of ANAB operations, all accredited laboratories are subject to the same accreditation process, including suspension and withdrawal procedures, regardless of their location.

3. Technical Qualifications:

a) ANAB is a member of the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC), and is a signatory of the IAF and ILAC multilateral recognition arrangements (MRAs). ANAB also is a signatory of the InterAmerican Accreditation Cooperation (IAAC) multi-lateral recognition arrangement (MLA) for testing and calibration, (ISO/IEC 17025), reference material producers (ISO Guide 34), inspection (ISO/IEC 17020), and management systems certification bodies (ISO/IEC 17021 for ISO 9001, ISO 14001, ISO 22000, ISO/IEC 27005, and ISO 13485).

ANAB also is a signatory of the Asia Pacific Laboratory Accreditation Cooperation (APLAC) MRA for testing and calibration (ISO/IEC 17025), reference material producers (ISO Guide 34), inspection (ISO/IEC 17020), and proficiency test providers (ISO/IEC 17043).

These recognitions demonstrate ANAB's competence and ability to assess and accredit conformity assessment bodies to the relevant standards. Certificates of recognition provided as an **Attachment A** to this document.

ANAB is independent non-profit, non-governmental organization governed by a board of directors. The board of directors is responsible for facilitating communication about accreditation programs, recommending creation of new accreditation programs, and providing annual budget approval. Members of the board represent stakeholders and include technical experts and industry and government representatives. A list of board members is publicly available on ANAB's website.

ANAB has a solid structure to ensure impartiality of operations. All employees, contract assessors, and

volunteer committee members sign a document indicating their commitment to follow ANAB policies and procedures, including those related to impartiality and avoidance of conflicts of interest. In addition, each step in the decision-making process is taken independently to ensure impartial and competent review.

b) ANAB is currently recognized by the FCC as Test Firm Accreditation Body (TFAB) for laboratories located in the United States. In addition, ANAB is listed by the National Institute for Standards and Technology (NIST) as a qualified accreditation body to for EMC/Telecom testing laboratories. The ANSI brand is recognized to accredit telecommunication certification bodies (TCBs) under the FCC program and by NIST under the National Voluntary Conformity Assessment Evaluation program (NVCASE) program.

ANAB has accredited 17 laboratories under this program, with several others performing similar or related work.

c) Unlike many accreditation bodies in the United States and elsewhere, ANAB has on-staff technical experts in most areas of testing. ANAB customers have direct access to employees who are experts in technical fields applicable to operations.

ANAB employs a dedicated accreditation manager responsible for EC/Radio/Telecom testing laboratories. This position is also responsible for direct contact with FCC and NIST and participation in biannual meetings. In addition, this individual participates in committees responsible for the development of ANSI C63 standards.

ANAB currently has five assessors approved for the EMC/Radio/Telecom areas and brief biographies are provided as an **Attachment B** to this document.

d) Policies and procedures for accreditation and designation of testing laboratories for FCC equipment authorization programs (provided as an **Attachment C** to this document):

ANAB follows the same general accreditation process for all its ISO/IEC 17025 customers. The process is documented in the ANAB manuals and procedures attached with this submission.

MA 2100, Accreditation Manual for Laboratory-Related Activities: Explains the operational activities and responsibilities of ANAB and its customers for laboratory-related programs (non-forensic).

AR 2250, ISO/IEC 17025 Testing Laboratories: Defines accreditation requirements for ISO/IEC 17025 testing laboratories (non-forensic). To be used in conjunction with MA 2100 (see Manuals above). Additional supplemental program-specific documents may apply.

SR 2412 – FCC Recognition of Accredited Testing Laboratories

All documents must be provided in English. During the on-site assessment, if needed arrangement are made for an interpreter(s). All interpreters must be approved by ANAB.

CL 2900.01 ISO/IEC 17025 General Requirements Checklist

CL 2031 FCC Checklist

FM 2804 Technical Competence Evaluation Form (OPIEF)

ANAB ISO/IEC 17025 Accreditation Process

1. Notification of Assessment:

Based on the proposed scope of accreditation, ANAB selects a technically qualified lead assessor and (as appropriate) assessment team. The assessor(s) are provided the laboratory name and scope to confirm no conflicts of interest exists between the laboratory and the assessor(s).

The laboratory is notified of the pending assessment and provided the assessor(s)' biographies. The laboratory must confirm no conflicts exist with the assessor(s) and is provided opportunity to accept or reject them. The laboratory must provide valid reason for rejecting an assessor.

ANAB informs the laboratory of the documents and information required prior to the on-site assessment. This information is detailed on the 17025 Laboratory Documentation Checklist.

The lead assessor and laboratory work together to schedule a mutually agreeable time for the assessment. For the initial assessment, the on-site visit must be scheduled within six months of acceptance of the cost estimate to avoid the need to re-apply. For surveillance and reassessments, the assessment must be scheduled within 30 days of the surveillance base date.

The lead assessor completes an assessment plan that details the schedule and exact plan for the assessment (arrival time, sections to cover, technical witness plan, etc.). The plan is provided to the laboratory for review and approval.

2. Documentation Review:

The laboratory is required to submit to ANAB all documentation identified on the ISO/IEC 17025 Laboratory Document Checklist within 30 days of the scheduled assessment. The lead assessor conducts a detailed review to ensure all applicable requirements are addressed. Additional documentation and specific methods may be requested.

Feedback is provided to the laboratory on any concerns from the document review prior to the assessment.

3. On-Site Assessment:

The assessment focuses on the laboratory's technical competence and internal quality system.

The quality system assessment involves examination of objective evidence supporting compliance with accreditation requirements. The assessment process verifies that the laboratory is operating a quality system in compliance with ISO/IEC 17025 accreditation requirements.

The technical assessment includes technical evaluation of the scope of accreditation and all supporting technical activities, such as in-house calibrations. The assessor verifies the technical competence of qualified laboratory staff to perform all technologies or parameters defined on the scope of accreditation.

During the closing meeting on the final day of the assessment, the lead assessor provides a summary of the outcome of the assessment and presents all non-compliances and/or opportunities for improvement (if applicable).

4. Corrective Action Procedures:

For any non-compliances identified during the assessment, the laboratory typically has 30 days to take corrective action and provide evidence to ANAB supporting the corrective action activities.

If necessary, the assessment team may recommend to ANAB a follow up assessment to ensure effective implementation of the corrective action. It is ANAB's decision to proceed with a follow up assessment.

If the laboratory disagrees with a non-compliance issued during the assessment or an accreditation decision, the laboratory can file a formal appeal or complaint.

5. Technical Review and Granting of Accreditation:

After ANAB receives from the laboratory the corrective action evidence supporting all non-compliances, ANAB and a member of a program-specific Technical Advisory Group (TAG) review the corrective action

responses to ensure each appropriate to support acceptance of the response and close the specific non-compliance.

If the laboratory corrective action responses are not initially accepted, ANAB sends a technical letter will to the laboratory requesting additional actions and supporting evidence. ANAB technical reviewers may contact the laboratory to discuss and resolve any outstanding concerns.

Following ANAB's acceptance of all corrective action responses and assurance that the laboratory has met the ISO/IEC 17025 accreditation requirements, both the scope and certificate are added to the Directory of Accredited Laboratories published at www.anab.org.

6. Maintaining Accreditation:

ANAB grants ISO/IEC 17025 accreditation for a two-year period based on the date of the initial issuance of the scope and certificate.

To maintain ISO/IEC 17025 accreditation, the laboratory is required to participate in an annual assessment activity. Following the initial two-year accreditation, assessment activities alternate annually, between full reassessments and surveillance assessment activities.

7. Notification of Changes:

All ANAB-accredited laboratories sign an agreement indicating their commitment to notify ANAB immediately of any changes in key personnel, ownership, legal status, location, or other change that could have an impact on the accreditation. The laboratory can request a change to the scope of accreditation at any time. ANAB reviews the change request and determines the steps necessary to make the change.

We look forward to providing any additional information in support of ANAB application.

Respectfully,

Natalia Larrimer

ANSI-ASQ National Accreditation Board

Attachment A: MRAs

ILAC MUTUAL RECOGNITION ARRANGEMENT

SIGNATORIES

We, the undersigned, endorse the terms of the ILAC Arrangement and undertake, to the best of our ability, fulfillment of its objectives.

Accreditation Body: ANSI-ASQ National Accreditation Board (ANAB)

Economy: USA

Scope and date:
Testing ISO/IEC 17025 – 14 September 2006
Calibration ISO/IEC 17025 – 14 September 2006
Inspection ISO/IEC 17020 – 5 December 2012

Authorised Representative:

Signature: _____ **Date:** 30 January 2015

Chairman, ILAC Arrangement Council:

Signature: _____ **Date:** 30 January 2015

Inter American Accreditation Cooperation

Be it known that the

ANSI ASQ National Accreditation Board
Dba ACLASS and Dba FQS

USA

Has been accepted as a Member of the

Inter American Accreditation Cooperation

Multi-lateral Recognition Arrangement

For
Accreditation Bodies of Inspection Bodies
(ISO/IEC 17020)

The Member on behalf of which this sheet is signed is committed to complying with the requirements and obligations of the IAAC MLA members

Keith Greenaway
Vice President
ANSI ASQ National
Accreditation Board

Ileana Martínez
Chair
IAAC

Alexander Pineda
Chair
IAAC MLA Group

Approved by the IAAC MLA Group on February 27, 2013.

APLAC MUTUAL RECOGNITION ARRANGEMENT

AN ARRANGEMENT TO GRANT RECOGNITION

Having fulfilled the requirements of the APLAC Mutual Recognition Arrangement, **ACLASS & FQS, United States of America,** is a signatory to the Arrangement.

APLAC MRA signatories:

(i) use equivalent procedures under ISO/IEC 17011 in the accreditation of laboratories against ISO/IEC 17025, medical laboratories against ISO 15189, inspection bodies against ISO/IEC 17020, reference material producers against ISO Guide 34 and proficiency testing providers against ISO/IEC 17043;

(ii) recognise, within the scope of recognition of this MRA, the accreditation of a laboratory, inspection body, reference material producer or proficiency testing provider by other signatories as being equivalent to an accreditation by its own organisation;

(iii) recommend and promote the acceptance by users in their economies of endorsed reports and certificates issued by laboratories, inspection bodies, reference material producers and proficiency testing providers accredited by APLAC MRA signatories;

(iv) investigate complaints initiated by a signatory resulting from reports or certificates issued by their accredited laboratories, inspection bodies, reference material producers or proficiency testing providers; and

(v) inform one another, as soon as possible, of any significant changes in the status and/or operational practices in their accreditation bodies.

Accreditation Body: ANSI-ASQ National Accreditation Board doing business as ACLASS & FQS - ACLASS & FQS

Economy: United States of America

Scope of Recognition: Testing/Calibration; RMP, Inspection; PTP

Date of Signing APLAC MRA: 13 September 2006; 11 December 2008; 5 December 2012; 25 June 2014

Nigel Jou
APLAC Chair

Inter American Accreditation Cooperation

Be it known that the

ANSI-ASQ National Accreditation Board, LLC
(D.b.a. ACLASS and D.b.a. FQS)

United States of America

Has been accepted as a Member of the

Inter American Accreditation Cooperation

Multi-lateral Recognition Arrangement

For

Accreditation Bodies of Calibration and Testing Laboratories (ISO/IEC 17025)

The Member on behalf of which this sheet is signed is committed to complying with the requirements and obligations of the IAAC MLA members

Keith Greenaway Vice-President ANSI-ASQ NAB	Beatriz Garcia Chair IAAC	Mauricio Soares Chair IAAC MLA Group

Approved by the IAAC General Assembly on August 11th, 2006

IAF
MULTILATERAL RECOGNITION ARRANGEMENT

This is to acknowledge that having fulfilled the requirements of the IAF Multilateral Recognition Arrangement,

American National Standards Institute - American Society for Quality National Accreditation Board (ANAB)

USA

is a signatory to the Arrangement.

Scope of recognition:

Environmental Management Systems (09 October 2004)

Quality Management Systems (22 January 1998)

The IAF MLA supports international trade by providing confidence that conformance to the requirements as defined in the standards of the relevant conformity assessment schemes for product and systems have been demonstrated.

Dr Thomas Facklam
Chairman
International Accreditation Forum, Inc.
9 October 2004

Inter American Accreditation Cooperation

Be it known that the

ANSI-ASQ National Accreditation Board, LLC
Dba ANAB

United States

Has been accepted as a Member of the

Inter American Accreditation Cooperation

Multi-lateral Recognition Arrangement

For

Accreditation Bodies of Quality Management System Certification Bodies

The Member on behalf of which this sheet is signed is committed to complying with the requirements and obligations of the IAAC MLA members

Randy Dougherty ANAB	Beatriz García IAAC Vice-Chair	Fabian Hernandez IAAC MLA Committee Chair

Approved by the IAAC General Assembly on March 31st, 2008
and signed in Asunción, Paraguay, on September 12th, 2008

Attachment B – Bios

Brian (Yeou Song) Lee earned his Ph.D. degree in Electrical and Computer Engineering. With over 27 years of working experiences with capacities in research, engineering, service, manufacturing, and management, he built extensive knowledge in many areas of calibration and testing disciplines, namely dimension, electromagnetic (LF, Microwave/RF, EMC/EMI/EMS), semiconductor, photovoltaic, wireless communication, time and frequency, reliability, medical, and optics

While working with the FCC on developing mutual recognitions of EMC labs in Taiwan, Brian developed knowledge of the FCC regulations (including Part 15, 18, 68, and 2), and the implementation for the Taiwan industries.

Brian is the chair of the IEEE high frequency measurement technical committee and sponsor chairs of IEEE standards. Brian was also the Vice Chair of the CNLA (i.e., TAF, Taiwan National Accreditation Body) electrical testing field including EMC, lecturer of the 1995 EMC Testing and Calibration and Future Trends Workshop-FCC/NVLAP Regulations (FCC Part 15, 18, 68) and EU EMC Directive. He is currently a voting/drafting member of IEEE, IEC, and ANSI standard committees.

Since 2006 EMC calibration and testing assessor for ANAB, A2LA and NVLAP. Conducted 2 assessments since the original recognition.

Victor Kuczynski has been doing assessments for various Accreditation Bodies for more than 17 years and with few exceptions, all assessed laboratories scope included FCC test methods. Starting his work with ANAB (L-A-B) in 2012. Additionally, for over 23 years through ANSI accredited C63 committee Victor has been actively participating in standard development related to FCC test methods. Victor conducted 5 assessments the original recognition.

Stephen Berger Chaired standards committees for ANSI C63.4, ANSI C63.17 and ANSI C63.19, all adopted by the FCC. Stephen conducted assessment of ~30 laboratories doing FCC testing as well as assessments of TCB's under ANSI. Stephen also chaired a workshop panel for the joint FCC/FDA Wireless Test Bed workshop and been invited to present to the FCC Technical Advisory Committee on several occasions.

Richard Reitz currently holds a position of the Director of Engineering in an independent testing laboratory performing regulatory compliance testing to FCC requirements, where he is been employed since December of 1983. Through the last 33 years Richard been directly involved with all aspects of FCC compliance testing and the regulatory approvals process. The three facilities within the organization have been accredited since the mid 1980 with hundreds of products tested for FCC's approval. These programs included (not all inclusive) FCC Part 15, Part 18, Part 74, Part 90, Part 95 and other FCC rule sections. Richard has been ANAB (L-A-B) contracted assessor for the past 5 years. Richard has not yet done any assessment under FCC requirements.

Raymond LaForge has a BEEE from NYU (1972) and an MSEE from University of RI (1975). He retired from the US Government after forty years of service. He spent 30 years of his 40 year career with the federal government working for the Federal Communications Commission. During the 30 years with the FCC he held various positions within the Office of Engineering and Technology, Chief of the FCC, FM Radio Branch concluding with fourteen years at the FCC Laboratory where he was Chief of Compliance Services Branch. Since 2011 Raymond his own company, RAL Engineering Inc., where he has performed about 50 Assessments for ANSI and ANAB to ISO/IEC quality standards, 17065, 17025 and 17020. About 35 of the 50 assessments were FCC related.

Attachment C – Program Documents

ACCREDITATION MANUAL FOR LABORATORY-RELATED ACTIVITIES (NON-FORENSICS)

AUTHORITY: VICE PRESIDENT

EFFECTIVE DATE: 2017/05/03

DOCUMENT NUMBER: **MA 2100**

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FOREWORD

Accreditation benefits organizations by providing assurance that they are consistently performing their work competently and according to appropriate standards. Accreditation provides a benchmark for maintaining that competence. Many organizations operate in isolation from their peers, and rarely, if ever, receive an independent technical evaluation as a measure of their performance.

A regular assessment checks aspects of an organization's operations related to consistently producing accurate and dependable data. Areas for improvement are identified and discussed, and a detailed report is provided at the end of each visit. When necessary, follow-up action is monitored so the organization is confident that it has taken the appropriate corrective action.

The ANSI-ASQ National Accreditation Board (ANAB) publishes a directory of accredited organizations, which includes contact details and information on accredited capabilities as a means for accredited customers to promote accredited services to their potential customers. Through a system of international agreements (see below), accredited organizations receive a form of international recognition, which allows their data, reports, and services to be more readily accepted in global markets.

This manual explains the operational activities and responsibilities of ANAB and its customers (excluding forensics and management systems certification bodies[1]). It provides direct reference to administrative process rules (PR series) documentation. This manual and its associated process rules are not citable during an assessment but are enforced through contractual agreements. This manual also provides reference to Accreditation Requirements (AR series) documentation that is followed to ensure the accreditation process meets the requirements of ISO/IEC 17011. Accreditation Requirements are citable during an assessment to ensure compliance with national and international standards and requirements. This manual also defines the relationship between ANAB and its accredited organizations (customers).

The term "customer" as used in this manual refers to any customer seeking accreditation from or accredited by ANAB.

All references to ISO/IEC, ISO, and ANAB documents and other controlled materials are to the current versions. Most ANAB documents are accessible free of charge at www.anab.org. ILAC documents are accessible free of charge at www.ilac.org.

AUTHORITY AND RECOGNITION

ANAB provides accreditation for ISO/IEC 17025 testing and calibration laboratories and forensic testing agencies, ISO/IEC 17020 inspection bodies and forensic inspection agencies, ISO 17034/ISO Guide 34 reference material producers, ISO/IEC 17043 proficiency test providers, and ISO 15189 medical test

[1]Accreditation requirements for ANAB management systems certification bodies and ANAB forensic science laboratories can be found in their respective accreditation manuals.

laboratories. In addition, ANAB accredits ISO/IEC 17021-1 management systems certification bodies, forensic-related bodies, and industry-specific programs.

ANAB is recognized as conforming with ISO/IEC 17011 and as such is a full member of the International Laboratory Accreditation Cooperation (ILAC), whereby ANAB is fully recognized by and recognizes ILAC signatories worldwide for the accreditation of customers. ANAB is a signatory of the Asia Pacific Laboratory Accreditation Cooperation (APLAC) Mutual Recognition Arrangement (MRA). ANAB also is a signatory of the InterAmerican Accreditation Cooperation (IAAC) Multilateral Recognition Arrangement (MLA). In addition, ANAB is recognized nationally by regulators and specifiers (automotive, aerospace, environment, industrial, manufacturing, medical, military, and government agencies) for program-specific requirements.

The further authority of ANAB is by virtue of the acceptance by others through international MRAs, its accredited customers, and the data and services ANAB provides.

ESTIMATE AND APPLICATION FOR ACCREDITATION

Applicant customers begin by contacting ANAB and completing the request for estimate of fees (RFQ). ANAB produces a confidential estimate of the cost of the accreditation based on the information submitted.

Estimates are based on several factors, including but not limited to the number of customer sites, the complexity of work defined on the proposed scope of accreditation, the number of technicians, and the type of services performed in house and/or off site.

ANAB sales and technical staff can assist with the application process. See www.anab.org for contact information.

ACCREDITATION CYCLE

ANAB follows a two-year accreditation cycle when performing assessment activities. Various assessment activities are performed annually by ANAB to ensure continuing compliance with accreditation requirements. The accreditation cycle and accreditation activities are designed to provide ANAB with a system to monitor the activities of the customer in order to maintain confidence that accreditation requirements continue to be fulfilled.

The two-year accreditation cycle consists of an initial accreditation assessment followed by a surveillance assessment activity the next year. During the first accreditation cycle, the surveillance assessment activity is typically required to be performed on site. At the end of the first accreditation cycle, a reassessment occurs, followed by a surveillance assessment (e.g., on site or possibly as a remote or desk assessment) one year later, and this cycle continues throughout each accreditation.

Under a contractual arrangement with regulators and/or specifiers and the accredited customer, ANAB may alter the accreditation cycle to a sector-specific required schedule. The requirements for such an altered cycle are detailed in ANAB supplemental requirements for a given sector-specific program.

The following procedure applies to all customers and provides details of ANAB assessment activities:

- PR 2303, Administrative Process Rule: Assessment Activities

OPTIONAL PRE-ASSESSMENT SERVICES

ANAB offers optional assessment activities prior to an initial accreditation assessment to help an applicant organization understand accreditation requirements and prepare for accreditation. These activities provide an opportunity for the customer to evaluate its preparedness for the initial accreditation assessment.

ANAB doesn ont provide consultation services because this is considered a conflict of interest for an accreditation body.

INTRODUCTORY VISIT

An introductory visit (IV) is an optional assessment activity performed by a single lead assessor ,typically for a half day to one assessment day. An Accreditation Manager allocates a lead assessor to perform an IV. The assessor presents and answers general questions regarding accreditation requirements, the assessment process, and/or forms. ANAB assessors are not permitted to provide consultancy. During an IV, the assessor may tour the facilities and point out obvious nonconformities. This is an informal educational visit without a formal report or documented findings.

PRACTICE ASSESSMENT

A practice assessment is an optional on-site service that essentially is an unofficial accreditation assessment. ANAB conducts an assessment just as it would conduct an actual accreditation assessment, documenting compliance and nonconformities on the forms used for an assessment. ANAB provides the customer these assessment records but maintains only those records that ensure and demonstrate impartiality of the customer's accreditation process. The customer may undergo a maximum of two practice assessments. Practice assessments have no influence on the accreditation assessment. Assessors assigned to conduct the practice assessment normally do not conduct the accreditation.

PLANNING VISIT

A planning visit (PV) is an optional assessment activity performed by a single lead assessor, typically for one assessment day. An Accreditation Manager allocates a lead assessor to perform the PV. This is an opportunity to have a one-on-one interface with a lead assessor without consequences and to address specific questions or concerns about the accreditation process. A PV may provide an opportunity to review nonconformities and opportunities identified during the initial assessment document review (AADR). A PV may include sample assessment questioning to prepare staff and may identify obvious nonconformities.

INITIAL ACCREDITATION ASSESSMENT

Leading up to the initial accreditation assessment, the customer is expected to have effectively implemented a quality system meeting the requirements of the applicable accreditation standard and applicable ANAB accreditation requirements.

Prior to the initial assessment, ANAB performs a **document review**. The document review typically is performed by the lead assessor assigned to the initial assessment activity. The lead assessor reviews the quality system documentation and determines if customer's documentation is ready for the initial assessment.

The customer shall be able to demonstrate technical competency and the ability to competently perform all items identified on the proposed scope of accreditation.

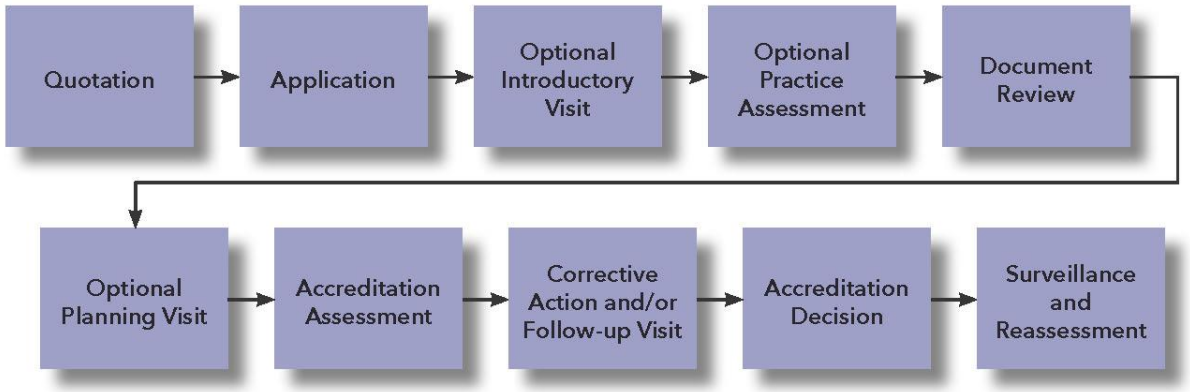
Within a 12-month period prior to the initial accreditation assessment, the customer shall complete an internal audit covering all elements of the applicable standards. This includes witnessing of a sampling of the proposed scope of accreditation.

Within a 12-month period prior to the initial accreditation assessment, the customer shall complete a management review covering the elements listed in the applicable standards.

Within a 12-month period (per Accreditation Requirements) prior to the initial accreditation assessment, the customer shall have completed at least one appropriate proficiency test or approved alternative.

The customer shall meet the requirements of all applicable ANAB accreditation program requirement documents.

ASSESSMENT PROCESS



The purpose of the assessment process is to determine the customer's compliance with the requirements of the applicable accreditation standard(s), ANAB accreditation requirements, and the technical competence to a declared scope of accreditation. Various assessment activity types are used, both on site and remotely, to evaluate conformance. Assessment activities include all locations where key activities of the customer are performed.

The ANAB assessment process was developed to sample in various details the customer's quality system and technical competence to a scope of accreditation. ANAB determines through interviews, reviewing documents and records, and witnessing of the scope of accreditation if the customer's system is effectively implemented and meets applicable requirements. The assessment team uses these assessment activities to determine if the customer continues to meet all ANAB requirements.

ANAB establishes surveillance and reassessment plans based on the customer's proven stability and competence. ANAB designs the reassessment and surveillance plans for each accredited organization to ensure representative samples of the scope of accreditation and management system are assessed on a regular basis.

ANAB may conduct surveillance assessments on a more frequent basis or schedule an early reassessment if ANAB determines this is warranted.

The customer may request and receive additional assessment activities in order to expand their scope during the accreditation cycle (see Scope of Accreditation below).

ASSESSMENT DELIVERABLES

The assessors will present to the customer the assessment summary, nonconformities (NCs) and agreed on scope of accreditation at the closing meeting after the assessment. These will be presented both in writing and orally to ensure a mutual understanding of the content for the deliverables.

ASSESSMENT SUMMARY

The assessor recommendation on accreditation and a summary of assessment activities, including any cited nonconformities, is provided to the customer and ANAB after the closing meeting of the assessment.

NONCONFORMITIES

ANAB presents any nonconformities (NCs) found during the assessment for the management system or technical operations supporting the scope of accreditation. These NCs and the anticipated timeframe for their closure are reviewed and formally presented to the customer during the closing meeting of each assessment activity.

OPPORTUNITIES FOR IMPROVEMENT

ANAB provides value to the customer by drafting potential assessment findings as opportunities for improvement (OFIs) when any are identified. An OFI is not an NC but is used to document an area of concern that does not have specific evidence to justify a finding and may help a customer improve operations. The customer is not required to respond to OFIs. Customers have a right to appeal any NC or accreditation decision (see Appeals and Complaints below).

DRAFT SCOPE OF ACCREDITATION

The draft scope of accreditation is formally confirmed and presented at the closing meeting. ANAB is in full control of the scope of accreditation and may choose to make changes as necessary during final review and processing.

POST-ASSESSMENT AND GRANTING OF ACCREDITATION

ANAB assessors, technical staff, and (when assigned) ANAB Accreditation Council Technical Advisory Group (AC TAG) member(s) review on a timely basis the assessment documentation to ensure that the assessment has taken place according to ANAB requirements. The technical review ensures that the customer has demonstrated adequate technical competence and provided to ANAB appropriate corrective action(s) for all issued nonconformities. ANAB technical staff also have the option, if necessary, to require that additional assessment activities be performed before an accreditation decision can be confirmed. This ensures the integrity and impartiality of the process.

Upon completion of the ANAB technical review, the decision to accredit the customer is made by ANAB technical staff based on the assessor recommendation, appropriate corrective action responses, and compliance with accreditation requirements.

After the decision to accredit is confirmed, ANAB sends the customer the certificate of accreditation, which includes the approved scope of accreditation. The customer is added to the directory of accredited customers on the ANAB website.

ANAB may conduct extraordinary assessment activities outside of a typical assessment cycle as a result of complaints, proficiency testing performance, location changes, organizational changes, and/or other situations in which it is necessary to ensure the integrity of the accreditation. ANAB advises the customer accordingly if such an extraordinary assessment is required.

NOTIFICATION OF CHANGES

According to ANAB signed agreements, the customer shall notify ANAB of any matters that may affect the customer's capability, the scope of accredited activities, or compliance with the requirements for accreditation. The customer shall use the ANAB notification process to formally document and submit a notification to ANAB.

The customer shall notify ANAB immediately of any changes in:

- Legal, commercial, or organizational status;
- Organization and management (e.g., key managerial staff or accounting contact);
- Policies or procedures that directly affect the validity of data;
- Physical location or premises;
- Changes to purchase order requirements and/or special invoicing methods required;
- Unsuccessful proficiency testing (or proficiency testing alternative) results;
- Key personnel, equipment, facilities, working environment, or other resources that would impact the validity of data, or the customer's ability to perform accredited work;

- Note: Key personnel is defined by ANAB to include the quality manager, technical manager, accounting contact, and anybody who is the only trained and authorized person to perform a technical activity supporting the scope, including uncertainty of measurement, and/or the facilitator of the proficiency testing/inter-laboratory comparisions scheme;
- Other significant changes affecting the customer quality system or technical operations and any other matter that may affect the customer's capability, scope, compliance with requirements, or other criteria of competence specified by ANAB.

Upon official receipt of customer notification, ANAB evaluates the impact on accreditation and may do any of the following:

- Make note within the ANAB system for future reference;
- Make a brief visit to the customer to assess the impact of the change;
- Request further proof of conformity with requirements;
- Revise the scope of accreditation;
- Perform a surveillance visit;
- Perform a full reassessment.

ASSESSMENT DELAYS

If a customer causes delay in the accreditation process, the following procedure applies:

- PR 2305, Administrative Process Rule: Delays Caused by the Customer, applies to all customers and provides the administrative process when a delay in the accreditation process is caused by the customer.

SCOPES OF ACCREDITATION

The scope of accreditation is a formal document owned by ANAB and issued to the accredited customer that defines the technical activities for which accreditation is sought. When accreditation has been granted, ANAB issues an approved final scope of accreditation.

PROPOSED SCOPE DEVELOPMENT

Prior to the initial assessment, the customer prepares a proposed scope of accreditation in accordance with the appropriate ANAB proposed scope instructions and using the appropriate scope of accreditation template.

The proposed scope of accreditation is a working document and is not an indication of accreditation status. Therefore, a proposed scope shall not be shared with any entity other than ANAB or its authorized representatives.

Scope instructions are located on the ANAB website (www.anab.org).

SCOPE MODIFICATION

The applicant or accredited customer can request changes to the scope of accreditation at any time. ANAB contacts the customer approximately three months prior to the expected yearly assessment activity to inquire about a possible change to the scope of accreditation. Unless ANAB is properly notified with adequate time prior to an assessment activity, the assessor may not be able to extend the scope during the assessment. The impact and cost of any scope change request is determined on a case-by-case basis.

Voluntary removal of scope items is unlikely to require more than administrative work by ANAB. Additions require review by ANAB technical staff to ensure the requirements of the scope item and ANAB are satisfied.

Technical competency to perform new scope activities is ensured by ANAB prior to addition to the scope of accreditation. This may require an on-site visit to verify the competency of the customer to perform the activities or may require only a technical review of documentation. A scope expansion visit may result in either partial or full approval and may result in identified nonconformities requiring corrective action prior to approval.

REQUIREMENT DOCUMENTS

This manual outlines the general processes for accreditation and refers to applicable accreditation requirements documents. ANAB accreditation requirements (AR series) documentation defines accreditation requirements. ANAB administrative process rules (PR series) documentation details key processes that support the accreditation requirements. This manual is to be used in conjunction with the following AR documents (as applicable) to fully define the requirements for accreditation.

ANAB offers accreditation to national and international conformity assessment standards and regulatory and industry-specific requirements. The customer shall own a copy of the applicable standard(s) and comply with the following accreditation requirement documents that define the requirements for accreditation specific to each program offered by ANAB:

- AR 2251, Accreditation Requirements: ISO/IEC 17025 Calibration Laboratories
- AR 2250, Accreditation Requirements: ISO/IEC 17025 Testing Laboratories
- AR 2252, Accreditation Requirements: ISO/IEC 17020 Inspection Bodies
- AR 2254, Accreditation Requirements: ISO Guide 34 Reference Material Producers
- AR 2258, Accreditation Requirements: ISO 17034 Reference Material Producers
- AR 2255, Accreditation Requirements: ISO/IEC 17043 Proficiency Test Providers
- AR 2253, Accreditation Requirements: ISO 15189 Medical Testing Laboratories

Supplemental requirements (SR series) documents apply to specific accreditation schemes developed by regulators and specifiers (automotive, aerospace, industrial, manufacturing, medical, military, government agencies) for program-specific requirements.

Technical requirements (TR series) may apply for specific fields of accreditation.

All ANAB documents that define accreditation requirements, supplemental requirements, or technical requirements are available on ANAB's website (www.anab.org).

CONTROL AND USE OF ACCREDITATION SYMBOL

Upon granting of accreditation, ANAB allows its accredited customers to refer to, promote, and advertise their accreditation status through the use of an accreditation symbol.

ANAB owns and controls the certificate of accreditation, scope of accreditation, and use of the ANAB logo and accreditation symbols.

ANAB-accredited customers can and are encouraged to display their accreditation status through use of the accreditation symbol, but this shall be done only on accredited work or promotional material referencing accredited work. The accreditation symbol shall not be displayed on work that deals only with non-accredited work.

Accredited customers benefit from the use of the accreditation symbol by the acceptance established through mutual recognition agreements (MRAs) among accreditation bodies.

Customers shall refer to accreditation or claim accreditation only while in active status. For all other statuses, the customer shall cease using the ANAB accreditation symbol in any way. This includes references on reports and/or certificates and all forms of advertising. Reports of work that covers both accredited and non-accredited work shall clearly distinguish this on the reports.

- AR 2201, Accreditation Requirements: Control and Use of Accreditation Symbol, applies to all customers and provides specific requirements for use of the accreditation symbol.

GUIDANCE DOCUMENTS

ANAB has published a series of accreditation guidance documents to assist in the understanding and application of accreditation requirements. ANAB guidance documents are available on request and on the ANAB website (www.anab.org).

ANAB encourages customers to review and understand all relevant guidance documents.

TRANSFER OF ACCREDITATION

Organizations accredited by other accreditation bodies can apply to transfer their accreditation from the other accreditation body to ANAB under strictly defined conditions. Transferring accreditation may save time and money when the current accreditation is considered in the application process. Only customers currently accredited by an ILAC MRA signatory accreditation body can qualify for transfer of accreditation. ANAB takes the necessary steps to determine eligibility and ensure a seamless transfer of accreditation.

- PR 2308, Administrative Process Rule: Transfer of Accreditation, applies to all customers and provides the specific administrative process for transfer of accreditation.

MULTI-SITE, TEMPORARY, AND MOBILE ACTIVITIES

ANAB offers accreditation to organizations made up of one legal entity with multiple locations or using mobile or temporary operations that all seek accreditation.

All facilities that belong to the entity seeking accreditation and deliver or support key activities need to be reviewed by ANAB to provide assurance they are subject to the same quality system and use the same quality manual, which must comply in all respects with the requirements of the applicable standard and accreditation requirements. In addition, ANAB reviews the organization to ensure key activities are performed as part of a single quality system to determine if a multi-site accreditation is appropriate or if separate accreditations are warranted for each site. ANAB requires that the entity nominate one person as the main point of contact related to accreditation activities.

Applicants that wish to seek multi-site accreditation are expected to declare their intention to seek a multi-site accreditation during the application process.

- PR 2307, Administrative Process Rule: Multi-Site Accreditation, applies and provides the specific administrative process for customers seeking multi-site accreditation.

CONFIDENTIALITY AND DISCLOSURE OF INFORMATION

All information ANAB acquires in relation to ANAB accreditation activities, except for accreditation information that is required to be made public and information made publicly available by the customer, is treated as confidential by all ANAB employees, agents, councils, and committees, and any contractors or subcontractors.

Such information will not be disclosed to any unauthorized party without the written consent of the customer, except when the law requires disclosure. When ANAB is required by law to release such information, the customer will be informed of the information provided.

ANAB may provide access to confidential information to accreditation peer evaluators from accreditation bodies recognized by ILAC, IAF, or regional cooperation (e.g., APLAC, IAAC) or other oversight bodies that have signed appropriate agreements to not disclose confidential information as required by specific schemes.

PUBLIC NOTICE AND INFORMATION

ANAB maintains on its website a publicly available directory of ANAB-accredited customers, including scopes of accreditation and information regarding suspensions and withdrawals of accreditation.

NOTIFICATION OF CHANGE IN ACCREDITATION REQUIREMENTS

ANAB will communicate to customers any changes in this accreditation manual and any additional accreditation requirements and procedures for accreditation, including the date on which the changes take

effect. ANAB's intent is to give customers a reasonable amount of time to document and implement any required changes.

Customer action in response to changes in accreditation requirements and procedures is normally reviewed at the next scheduled assessment (or first assessment following any implementation period), unless the changes to the accreditation requirements warrant earlier verification, as determined by ANAB.

Accreditation requirements will be published on ANAB's website (www.anab.org).

ACCREDITATION STATUS

All ANAB customers are identified on the website by an accreditation status. The accreditation status categories are active, inactive, voluntary withdrawal, suspension, and termination.

In the event that ANAB decides to change the accreditation status of a customer from active to any other status, ANAB will notify the customer of the reasons for such action.

- PR 2301, Administrative Process Rule: Accreditation Status, applies to all customers and provides the specific administrative process for accreditation status.

APPEALS AND COMPLAINTS

ANAB has an established process in place for reviewing and processing appeals and complaints.

Customers can submit a formal complaint about any aspect of the accreditation process. ANAB may receive a complaint from any source, such as a customer, another accreditation body, or a stakeholder, via verbal communication, email, or the ANAB survey form. ANAB will take action to ensure a clear understanding of the complaint and take action to appropriately resolve it.

Customers can submit a formal appeal about any assessment finding or decision. ANAB will take action to ensure a clear understanding of the appeal and take action to appropriately resolve it.

Notification of an appeal shall be provided to ANAB within 30 days of the reported NC, change in accreditation status, or accreditation decision.

- PR 6000, Administrative Process Rule: Appeals and Complaints, applies to all customers and provides the specific administrative process for the appeals and complaints process.

FEES RELATING TO ACCREDITATION

ANAB invoices various fees based on the assessment activity and travel. Customers are directed to the below PR document for details.

- PR 2306, Administrative Process Rule: Fees Relating to Accreditation, applies to all customers and provides the specific administrative process for the fees relating to the accreditation process.

RESPONSIBILITIES OF THE CUSTOMER

The signed application for accreditation and the requirements of the relevant accreditation program establish the relationship between ANAB and the conformity assessment body (customer). The application for each accreditation program contains the responsibilities and obligations for the customer.

The ANAB logo is a registered trademark solely owned by ANAB. As long as the customer maintains its status as accredited by ANAB pursuant to ANAB's accreditation requirements, the customer will have the non-exclusive and non-transferable right to use the certificate and scope of accreditation and the accreditation symbol (but not the ANAB logo).

OBLIGATIONS OF THE CUSTOMER

The customer will afford ANAB any accommodation and cooperation necessary to enable ANAB to verify compliance with the requirements for accreditation.

ANAB requires that its customers:

- Comply with the applicable standards and accreditation requirements;[2]
- Comply with all relevant provisions of ISO/IEC 17011 as defined in ANAB requirement documents;
- Comply with all other relevant ANAB requirements;
- Make all necessary arrangements to cooperate fully and supply to ANAB all information and documentation needed before and during the accreditation process;
- Claim that it is accredited only in respect to services and locations covered by the scope of accreditation;
- Pay accreditation fees before receiving initial and ongoing accreditation;
- Not use its accreditation in a way that brings ANAB into disrepute and not make any statement about its accreditation that could be considered misleading or unauthorized;
- Upon suspension or withdrawal of accreditation (however determined), cease using any advertising containing any reference thereto and return any certificates of accreditation to ANAB as requested;
- Not use its accreditation to imply ANAB approval of any product, process, system, and/or person and/or service;
- Endeavor to ensure that no certificate or report of accredited work or any part thereof is used in a misleading manner;
- Comply with ANAB requirements when referring to its accreditation status in advertising, brochures or other documents, or other communications.

[2]If applicable, customers shall comply with sector-specific supplemental and technical requirements as defined in relevant SR series and TR series accreditation documentation.

RESPONSIBILITIES OF ANAB

IMPARTIALITY

ANAB is organized, structured, and operated to safeguard the objectivity and impartiality of its activities. Conformity assessment services and consultancy cannot be provided by ANAB or its employees in order to uphold impartiality. Each decision on accreditation is taken by a competent person or persons different from those who carried out the assessment. ANAB ensures that the activities of its related bodies do not compromise the confidentiality, objectivity, and impartiality of its accreditations.

ETHICS AND CODE OF CONDUCT

All ANAB contract, leased, temporary, and permanent employees, experts, assessors, and instructors agree to their willingness to observe and be bound by the following to:

- Act in a strictly trustworthy and unbiased manner in relation to both ANAB and any organizations involved in an assessment by them or personnel for whom they are responsible;
- Disclose any relationships they may have with the organization to be assessed before undertaking any assessment function concerning said organization;
- Not accept any inducement, gift, commission, discount, or any other profit from the organization assessed or its representatives or from any other interested person, nor knowingly allow personnel for whom they are responsible to do so;
- Maintain confidentiality and not disclose the findings or any part of them, the assessment team responsible, or any other information gained in the course of an assessment process to any third party, unless authorized in writing by both the assessed organization and ANAB;
- Not act in any way prejudicial to the reputation or interests of ANAB or to the assessed organization.

CONFLICT OF INTEREST

As an accreditation body, ANAB ensures that its activities do not compromise the confidentiality, objectivity, and impartiality of its accreditations. Assessors, technical experts, and Accreditation Council members ensure the impartiality of their conduct by declaring no conflict of interest with any activity related to the customer and the accreditation process.

As a result, all assessors, technical experts, contractors, and AC TAG members:

- Disclose to ANAB any professional, financial, and/or work-related interest that could be construed as a potential conflict of interest;
- Agree to hold in confidence all information received from each customer and ANAB unless the law requires such information disclosed without ANAB's consent;
- Declare that they understand and agree with the ANAB assessor manual that ensures that they are not subject to any undue influences or pressure that might affect their objectivity and integrity;
- Act objectively and are be free from any undue commercial, financial, and/or other pressures that could compromise impartiality;
- Will not consult with applicants or customers that they have assessed at least until the time of the responsibilities for the issues of that particular customer has been fully discharged. ANAB

employees will not consult with customers. Assessors and technical experts contracted to review technical packages will disclose immediately if they or their affiliates have consulted directly with any customer that may give the appearance of a conflict of interest, and will not make any decision related to that customer;

- Maintain as confidential all contract monetary information concerning ANAB that has not otherwise been made public by ANAB;
- In the event of any alleged breach of this code, cooperate fully in any formal inquiry procedure.

REVISION HISTORY

Revision Level	Revision Date	Description
Original Release	2017/05/03	Original Release. Replaces the legacy ANAB and L-A-B accreditation manuals.

ACCREDITATION REQUIREMENTS: ISO/IEC 17025 TESTING LABORATORIES (NON-FORENSICS)

AUTHORITY: VICE PRESIDENT

EFFECTIVE DATE: 2017/05/15

DOCUMENT NUMBER: **AR 2250**

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INTRODUCTION

This document defines accreditation requirements for the ISO/IEC 17025 – testing laboratories (non-forensic). This document is intended to be used in conjunction with the ANAB MA 2100 - Accreditation Manual for Laboratory Related Activities (non-forensic). Additional supplemental program-specific documents may apply. Only statements in this document with a 'shall" represent requirements by ANAB.

REFERENCES

MA 2100, ANAB Accreditation Manual for Laboratory Related Activities (non-forensic).

ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories.

ISO/IEC 17043:2010, General requirements for proficiency testing (providers).

JCGM 200, International vocabulary of metrology – Basic and general concepts and associated terms (VIM).

TERMS AND DEFINITIONS

Authoritative source: For ANAB purposes, an authoritative source is known to be reliable because its authority or authenticity is widely recognized by experts in the field. These may be organizations such as government regulatory agencies (EPA, FDA, USDA, etc.), standard development organizations (AOAC, ASTM, USP, ISO, AABB), or organizations considered by experts to be industry leaders.

Calibration and measurement capability (CMC): Calibration and measurement capability available to customers under normal conditions (a) as published in the BIPM key comparison database (KCDB) of the CIPM MRA or (b) as described in the laboratory's scope of accreditation granted by a signatory of the ILAC Arrangement. [CIPM MRA-D-04, Version 2 (2011), Calibration and Measurement Capabilities in the context of the CIPM.]

Competency: Possession of required skill, knowledge, qualification, or capacity.

Conformity assessment activity: For ANAB purposes, these are defined as calibration, testing, inspection, PTP, RMP, or medical as identified in the scope of accreditation.

Major field: For ANAB purposes, major fields are defined as the categories of testing as identified in the scope of accreditation (e.g. Electrical, Mechanical, Thermodynamic, …).

National Metrology Institute (NMI): National Metrology Institutes (NMIs) and Designated Institutes (DI) maintain standards in countries (or regions) all over the world. Throughout this document, the term "NMI" is used to cover both National Metrology Institutes and Designated Institutes.

Related discipline: For ANAB purposes, related disciplines further defines the major field.

1. PROFICIENCY TESTING

1.1. General Requirements

1.1.1. Laboratories shall participate in appropriate PT/ILC activities or alternatives (defined below) which represents the parameters, ranges, measurements, test technologies, inspections, methods, and uncertainty of measurement described in the scope of accreditation.

1.1.2. Laboratories shall maintain a documented plan that assures participation for the current year, and at least the next three years covering a representative sampling of activities within each major field identified in the scope of accreditation.

1.1.3. Laboratories shall investigate any results found outside of predefined performance criteria, such as unsatisfactory results.

a. Laboratories shall promptly notify ANAB of unsatisfactory results;

b. When appropriate, corrective action shall be performed;

c. A record of the investigation summary and conclusion shall be retained.

1.1.4. Laboratories shall maintain records of their participation on a rolling four-year basis.

1.1.5. Laboratories shall ensure that PT activities are not always performed by the same person if other qualified personnel in the system perform accredited work.

1.2. Types of Activities

1.2.1. If other factors are similar, laboratories shall select, when available, PT/ILC providers that are accredited to ISO/IEC 17043 by ANAB or another accreditation body that is a signatory of the APLAC or IAAC MRA for PTP.

1.2.2. When ISO/IEC 17043 accredited PT/ILC providers are available but not used, the laboratory shall seek written ANAB approval for each PT/ILC scheme. This written ANAB approval shall be documented prior to participation.

1.2.3. When ISO/IEC 17043 accredited PT/ILC providers are not available or appropriate, laboratories shall use programs that operate in accordance with ISO/IEC 17043, if available. The laboratory shall seek written ANAB approval for each PT/ILC or alternative scheme.

1.3. Frequency of Activities

1.3.1. Laboratories shall participate in at least one approved PT/ILC activity or alternative each calendar year.

1.3.2. Laboratories shall perform a PT/ILC activity or alternative covering a representative sampling of activities within each major field in the scope of accreditation for each rolling four-year period.

1.4. Initial Accreditation Requirements

1.4.1. Before accreditation can be granted, applicant laboratories shall have performed satisfactorily in at least one approved PT/ILC or alternative activity within the previous 12 months. Applicant laboratories shall provide reported results as evidence by either a preliminary or final report issued by an approved provider. Evidence of PT participation and submission of data may be sufficient for initial

accreditation. In such cases, failure to submit to ANAB an official report of results within six months of accreditation will risk suspension of accreditation by the laboratory

2. METROLOGICAL TRACEABILITY

2.1. Laboratories shall ensure that all testing results are traceable whenever possible through NIST or another National Metrology Institute (NMI) to the International System of Units (SI units). When this is not feasible or possible, traceability to consensus standards, reference materials, or defined methods shall be sought. Metrological traceability conveys international confidence on two levels. One is the chain of comparisons to SI units to assure measuring devices or standards meet their manufacturing specifications. A second is to convey confidence in the measuring errors or variability for those devices or materials (typically reported as a measurement uncertainty).

2.2. Demonstration of Metrological Traceability

2.2.1. Equipment and reference standards that must be calibrated shall demonstrate traceability through one of the following:

2.2.1.1. National Metrology Institute (NMI): Laboratories may use NIST or, when appropriate, another NMI. The laboratory shall use an NMI whose service is suitable for the intended need and is covered by the CIPM MRA. Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB, which includes the range and uncertainty for each listed service.

2.2.1.2. Intrinsic Standard: When intrinsic standards are used, the laboratory shall demonstrate by measurement assurance techniques, inter-laboratory comparison, or other suitable means that the intrinsic measurement results are correlated with an NMI (e.g., Josephson Junction, Triple-Point devices).

2.2.1.3. Traceability from Weights and Measures Laboratory: ANAB applicant and accredited labs can use a national, state, or provincial weights and measure laboratory that is recognized and/or traceable to any recognized NMI. Evidence of recognition and/or traceability shall be available during the assessment.

2.2.1.4. External ISO/IEC 17025 Accredited Calibration Laboratory: In the vast majority of cases, an external calibration is used. Laboratories shall use ISO/IEC 17025 accredited calibration laboratory services whenever available. ISO/IEC 17025 accredited calibration laboratories are accredited by ANAB or an accreditation body that is recognized as a signatory of the ILAC MRA.

2.2.1.4.1. When using accredited calibration laboratory services, the calibration certificates shall be accompanied by a recognized accreditation body symbol or otherwise refer to accredited status to be considered satisfactory for traceability purposes.

2.2.1.5. When an applicant or accredited laboratory seeks to submit reference standards and equipment to a calibration provider not covered by the traceability hierarchy above, the laboratory shall apply for the approval of that non-accredited calibration provider by submitting the following:

a. An unbroken chain of comparisons going back to a standard acceptable to the parties, usually a national or international standard.

b. Proof that measurement uncertainty throughout the traceability chain has been calculated according to accepted methods and stated so an overall uncertainty for the whole chain can be calculated.

c. Proof that each step in the chain has been performed according to documented and generally acknowledged procedures, including documenting results (before and after data).

d. Evidence of technical competence of the non-accredited providers.

e. Proof that traceability is to SI.

f. Evidence that calibrations have been repeated at appropriate intervals.

3. METROLOGICAL TRACEABILITY USING REFERENCE MATERIALS

3.1. Laboratories shall ensure that all testing and calibration results are traceable whenever possible through NIST or other National Metrology Institute (NMI) to the International System of Units (SI units). When this is not feasible or possible, traceability to consensus standards, reference materials, or defined methods shall be sought.

3.2. Demonstration of Metrological Traceability Using Reference Materials

3.2.1. When laboratories obtain measurement traceability by using reference materials, they shall use one of the following:

a. Certified Reference Materials (CRMs) from a reference material producer (RMP) accredited to ISO Guide 34 or ISO 17034 by ANAB or other MRA signatory accreditation body.

b. Standard Reference Materials® (SRM) from NIST (called under trademark);

c. CRM from another National Metrological Institute (NMI). Use of any CIPM-active NMI may be acceptable.

3.2.2. If traceability per 3.2.1 is not possible, laboratories shall obtain measurement traceability from authoritative sources.

a. Laboratories shall determine that reference materials obtained from authoritative sources are fit for intended uses in accordance with established and validated procedures.

3.2.3. If traceability per 3.2.1 or 3.2.2 is not possible, or when no methods or reference materials are available, laboratories shall develop reference methods or materials from internal validation.

a. Laboratories shall validate methods and determine fitness for use.

3.3. Reference material shall not be altered from their original state from the manufacturer without validation that they are still suitable for use. Documentation shall be available of this validation.

3.4. Because many CRMs and RMs are qualitative or have nominal values, traceability is still relevant for the CRM or RM but not the associated quantitative uncertainty.

4. UNCERTAINTY OF MEASUREMENT

4.1. Laboratories shall have a documented uncertainty of measurement procedure and be able to demonstrate to ANAB during an assessment that they can apply their uncertainty of measurement calculations procedure as required by ISO/IEC 17025, section 5.4.6, and ANAB.

4.2. Dimensional testing (inspection) laboratories shall follow ANAB technical requirements in determining the calibration measurement capability and measurement uncertainty. ANAB has provided a separate document for these requirements.

4.3. In addition, ANAB has a guidance document to further the understanding of measurement uncertainty and its application for testing laboratories. Accredited ANAB testing laboratories for ISO/IEC 17025 are expected to understand and follow relavent guidance. ANAB provides specific guidance on the application of measurement uncertainty related to a testing laboratories test categories.

5. IN-HOUSE CALIBRATIONS

5.1. For the purpose of ensuring traceability of measurement, an accredited testing laboratory can calibrate its own equipment that supports an accredited parameter in the scope; in this case, the laboratory shall follow the relevant requirements ISO/IEC 17025 and shall meet the following requirements:

5.1.1. An appropriate environment for carrying out the calibration;

5.1.2. Appropriately trained personnel to both carry out and check the calibrations;

5.1.3. Demonstrate competency to perform the calibrations undertaken;

5.1.4. Reference standards, certified reference materials, or reference measuring instruments are traceable with appropriate measurement uncertainties;

5.1.5. Documented procedure for each type of calibration;

5.1.6. Appropriate means of recording and reporting the data and results of any calculations according to the requirements of ISO/IEC 17025;

5.1.7. Procedure for calculating the measurement uncertainty for each calibration, and be able to demonstrate to ANAB during an assessment that the laboratory has applied the uncertainty measurement calculations.

5.2. The laboratory shall maintain a list of in-house calibrations documenting the traceability of the measurements associated with the scope technologies.

REVISION HISTORY

Revision Level	Effective Date	Description
Original Release	2017/05/15	Combines legacy ANAB and L-A-B requirements.

SUPPLEMENTAL ACCREDIATION REQUIREMENTS:

FCC RECOGNITION OF ACCREDITED TESTING LABORATORIES (FCC PROGRAM)

AUTHORITY: VICE PRESIDENT

EFFECTIVE DATE: 2017/06/14

DOCUMENT NUMBER: **SR 2412**

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INTRODUCTION

ANAB has developed a voluntary accreditation program for the FCC-recognition of ANAB-accredited ISO/IEC 17025 accredited testing laboratories. ANAB is recognized by the Federal Communications Commission (FCC) Office of Engineering and Technology (OET) Laboratory Division to designate ISO/IEC 17025 accredited Testing Laboratories in the United States. The FCC requires that FCC-recognized accredited testing laboratories be used to test products for either certification or Declaration of Conformity (DoC) in support of the Commission's equipment authorization program as defined in FCC regulations.

REFERENCES

KDB 974614 – D01 Accredited Test Lab Roles and Resp v04 – Accredited Testing Laboratory Program Roles and Responsibilities, June 16, 2016

KDB 974614 D02 Accreditation Body Recognition v01 – OET Procedures for the recognition of Laboratory Accreditation Bodies, June 16, 2016

TERMS AND DEFINITIONS

CISPR: Comité International Spécial des Perturbations Radioélectriques (International Special Committee on Radio Interference).

OATS: Open Area Test Site

LISN: Line Impedance Stabilization Network

S_{VSWR}**:** Sine Voltage Standing Wave Ratio

1. LABORATORY REQUIREMENTS

1.1. A facility layout plan of the laboratory which includes complete description of the laboratory's OATS(s) shall be available with drawings and descriptions of the surrounding areas and adjacent structures, if applicable. If a facility other than an OATS is used, a complete description shall be available along with documentation of equivalence.

1.2. OATS site attenuation shall be checked in accordance with ANSI C63.4-2014 at least once yearly and complete records shall be maintained and be available for review.

1.3. VSWR of the site (above 1 GHz) must be evaluated.

1.4. Vertical conducting planes (where used) shall be properly bonded to the horizontal reference ground plane in accordance with ANSI C63.4-2014.

1.5. Turntables and Antenna Positioners shall be properly installed in accordance with ANSI C63.4-2014.

1.6. Antennas used for compliance measurements shall be calibrated in accordance with ANSI C63.5-2006.

- Standard gain horns do not require periodic recalibration unless damaged or deterioration is known or suspected. If a standard gain horn is not periodically recalibrated, its critical dimensions shall be verified and documented annually.
- Precision broadband omnidirectional (Biconical) antennas used for SVSWR site validation and complying with construction and pattern requirements specified in CISPR 16-1-4:2014-04 do not require periodic recalibration unless deterioration is known or suspected.

1.7. All Attenuators, RF cables, pre-amplifiers, switches, and terminators shall be characterized in accordance with ANSI C63.4-2014.

1.8. Each LISN shall be calibrated for insertion loss and impedance at least yearly.

1.9. Instrument calibration shall be confirmed in the first year of deployment. Subsequent recalibration intervals may be extended based on the review of calibration data relative to the instrument manufacturer's recommendation as appropriate up to three years.

1.10. Laboratories in countries that have not joined the APECTEL MRA with the U.S. must contact ANAB to confirm whether ANAB has been recognized to designate laboratories in their country. ANAB will only designate multi-site organizations to the FCC within a single country.

1.10.1 ANAB will the follow the standard process for designation for Accredited laboratories in countries with which the U.S. signs the MRA.

2. ASSESSOR RESPONSIBILITIES

2.1. The assessor will complete the current FCC Technical Assessment Checklist in addition to the normal assessment documentation.

2.2. The assessor will confirm the scope identifies FCC compliant testing only as defined in table 1. All other testing will be documented in separate tables on the draft scope of accreditation.

Table 1

Testing performed in support of FCC DoC and certification approval procedures

Type of Device Examples	Scope of Accreditation	Supporting FCC Guidance	Comments
Unintentional Radiators (FCC Part 15, Subpart B)	• ANSI C63.4-2014		
Industrial, Scientific, and Medical Equipment (FCC Part 18) • Consumer ISM equipment	• FCC MP-5, (February 1986) •		
Intentional Radiators (FCC Part 15 Subpart C)	• ANSI C63.10-2013		
UPCS (FCC Part 15, Subpart D) •Unlicensed Personal Communication Systems devices	• ANSI C63.17-2013		
U-NII without DFS Intentional Radiators (FCC Part 15, Subpart E) •Unlicensed National Information Infrastructure Devices (U-NII without DFS)	• ANSI C63.10-2013	KDB Publication 789033	

Testing performed in support of FCC DoC and certification approval procedures

Type of Device Examples	Scope of Accreditation	Supporting FCC Guidance	Comments
U-NII with DFS Intentional Radiators (FCC Part 15 Subpart E) • Unlicensed National Information Infrastructure U-NII) Devices with Dynamic Frequency Selection (DFS)	• FCC KDB Publication 905462 D02 UNII DFS Compliance Procedures New Rules v01 (April 8, 2016)		
UWB Intentional Radiators (FCC Part 15, Subpart F) •Ultra-wideband Operation	• ANSI C63.10-2013		
BPL Intentional Radiators (FCC Part 15, Subpart G) •Access Broadband Over Power Line (Access BPL)	• ANSI C63.10-2013		
White Space Device Intentional Radiators (FCC Part 15, Subpart H) •White Space Devices	• ANSI C63.10-2013		
Commercial Mobile Services (FCC Licensed Radio Service Equipment) •Part 22 (cellular) •Part 24 •Part 25 (non-microwave) •Part 27	• ANSI/TIA-603-D • TIA-102.CAAA-D		
General Mobile Radio Services (FCC Licensed Radio Service Equipment) •Part 22 (non-cellular) •Part 90 (non-microwave) •Part 95 •Part 97 •Part 101 (non-microwave)	• ANSI/TIA-603-D • TIA-102.CAAA-D	Microwave Frequencies, as used in this part, refers to frequencies of 890 MHz and above.	
Citizens Broadband Radio Services (FCC Licensed Radio Service Equipment) •Part 96	• ANSI/TIA-603-D • TIA-102.CAAA-D		
Maritime and Aviation Radio Services (FCC Licensed Radio Service Equipment) •Part 80 •Part 87	• ANSI/TIA-603-D		
Microwave and Millimeter Bands Radio Services (FCC Licensed Radio Service Equipment) •Part 25 •Part 74 •Part 90 (90Y, 90Z, DSRC) •Part 101	• ANSI/TIA-603-D • TIA-102.CAAA-D		
Broadcast Radio Services (FCC Licensed Radio Service Equipment) •Part 73 •Part 74 (non-microwave)	• ANSI/TIA-603-D • TIA-102.CAAA-D		

Testing performed in support of FCC DoC and certification approval procedures

Type of Device Examples	Scope of Accreditation	Supporting FCC Guidance	Comments
RF Exposure •Devices subject to SAR requirements	• IEEE Std 1528™-2013	KDB Publication 865664 KDB Publication 447498	
Hearing Aid Compatibility (Part 20) •HAC for Commercial mobile services	• ANSI C63.19-2007; or • ANSI C63.19-2011		
Signal Boosters (Part 20) •Wideband Consumer signal boosters •Provider-specific signal boosters •Industrial signal boosters	• FCC KDB Publication 935210 D03 Signal Booster Measurements v04(February 12, 2016) • FCC KDB Publication 935210 D04 Provider Specific Booster Measurements v02 (February 12, 2016) • FCC KDB Publication 935210 D05 Indus Booster Basic Meas v01r01 (February 12, 2016)		

2.3. The assessor will confirm the revisions and/or dates of all test methods referenced on the draft scope of accreditation. Electrical EMC/EMI scopes of accreditation will identify revision and/or date for all test methods.

3. ANAB RESPONSIBILITIES

3.1. Upon granting accreditation, ANAB, as a designating authority (DA) in the United States, will designate the laboratory to the FCC per FCC instructions if the laboratory is based in the United States.

- A non-U.S. laboratory must request designation by the DA for their country. ANAB will forward requested information to that DA at the request of the laboratory.

3.2. ANAB will maintain the designation on the FCC website while the laboratory is accredited for this testing.

3.3. ANAB will designate laboratories to the FCC only in non-MRA countries where ANAB is recognized by the FCC to do so.

3.3.1 Laboratories are subject to all applicable ANAB processes and procedures regardless of where the laboratories are located.

3.3.2 ANAB will inform accredited laboratories in a country with which the U.S. has signs the MRA and will then follow the procedures defined within the MRA.

3.3.3 ANAB may grant extensions to accreditations in cooperation with the DA of that country to facilitate a smooth transfer of accreditation.

REVISION HISTORY

Revision Level	Revision Date	Description
Original Release	2017/04/04	Original release.
1	2017/05/19	Revised in response to FCC.
2	2017/06/13	Revised in response to the FCC
3	2017/06/14	Revised in response to the FCC

ISO/IEC 17025 – General Accreditation Requirements

Laboratory Information

Company Name	
Laboratory Location(s)	
Completed By / Date	

Assessor Information

Assessor Name(s)	
Assessment Type	
Date of Assessment	

- This checklist is to be used as part of the ANAB 17025 General Accreditation Requirements.
- This checklist includes the requirements of:
    - ISO/IEC 17025:2005 - General Requirements for the Competence of Testing and Calibration Laboratories;
    - Accreditation Requirements (AR) for calibration, testing and use of accredited symbol.
- The requirements identified within this checklist are summarized from the referenced standards.
- This checklist will be used for the following assessment activities:
    - AADR – Accreditation Assessment Document Review;
    - AA – Accreditation Assessment (initial);
    - TRA – Transfer Reassessment;
    - RA – Reassessment.

17025 Element	Requirement	Customer Document Reference	Conformance C | NC | NA	Comments on Conformance
4	**Management Requirements**			
4.1	**Organization**			
4.1.1	Is the laboratory/parent organization an entity that can be held legally responsible?			
4.1.2	Is the laboratory carrying out testing/calibration activities to meet the requirements of the International Standard and satisfying the needs of customers, regulatory authorities, or organizations providing recognition?			
4.1.3	Does the laboratory's management system cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary/mobile facilities?			
4.1.4	If the laboratory is part of an organization performing activities other than testing or calibration, are the responsibilities of key personnel in the organization that have an involvement or influence on testing or calibration activities defined in order to identify potential conflicts of interest? ***Objective evidence is required**			
4.1.5	The laboratory shall:			
a)	Does the laboratory have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance, and improvement of the management system, and to identify the occurrence of departures from the management			

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17025 Element	Requirement	Customer Document Reference	Conformance C | NC | NA	Comments on Conformance
	system or from the **procedures** for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2)?			
* b)	Does the laboratory have arrangements to ensure management and personnel are free from any undue internal/external commercial, financial and other pressures and influences that may adversely affect the quality of their work?			
* c)	Does the laboratory have **policies** and **procedures** to ensure protection of customers' confidential information and proprietary rights, including **procedures** for protecting electronic storage and transmission of results? ***Objective evidence is required**			
* d)	Does the laboratory have **policies** and **procedures** to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity? ***Objective evidence is required**			
* e)	Does the laboratory define the organization and management structure of the laboratory, its place in any parent organization, and relationships among quality management, technical operations, and support services? ***Objective evidence is required**			
* f)	Does the laboratory specify the responsibility, authority, and interrelationships of all personnel who manage, perform, or verify work affecting the quality of tests/calibrations? ***Objective evidence is required**			

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* g)	Does the laboratory provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and **procedures**, the purpose of each test and/or calibration, and with the assessment of the test or calibration results?			
* h)	Does the laboratory have technical management which has overall responsibility for technical operations and the provision of the resources needed to ensure the required quality of laboratory operations?			
* i)	Does the laboratory have a member of staff who is appointed as quality manager (however named) who, irrespective of other duties and responsibilities, has the defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; does the quality manager have direct access to the highest level of management at which decisions are made on laboratory **Policy** or resources? ***Objective evidence is required**			
j)	Does the laboratory have deputies appointed for key managerial personnel (see note)? *Objective evidence is required			
k)	Does the laboratory ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system?			

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* 4.1.6	Does top management ensure that appropriate communication processes are established in the laboratory and that communication occurs regarding the effectiveness of the management system?			
4.2	**Quality System**			
4.2.1	Has the laboratory established, implemented and maintained a quality system appropriate to its scope of activity and communicated, understood, available and implemented by appropriate personnel?			
4.2.2	Are the laboratory's management system **policies** defined in a quality manual (however named), including a quality **policy** statement? ***Objective evidence is required**			
4.2.2	Is the quality **policy** statement issued under the authority of top management? ***Objective evidence is required**			
4.2.2	Are overall objectives established in the management system and reviewed during management review? ***Objective evidence is required**			
* 4.2.2	A quality **Policy** statement shall be issued under the authority of the chief executive and shall include:			
* a)	Does the quality **policy** statement include management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers?			

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* b)	Does the quality **policy** statement include management's statement of the laboratory's standard of service?			
* c)	Does the quality **policy** statement include the purpose of the management system related to quality?			
* d)	Does the quality **policy** statement include a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the **policies** and **procedures** in their work?			
* e)	Does the quality **policy** statement include laboratory management's commitment to comply with the International Standard and to continually improve the effectiveness of the management system?			
4.2.3	Does evidence exist showing top management is committed to the development and implementation of the management system and to continually improving its effectiveness?			
4.2.4	Does top management communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements?			
* 4.2.5	Does the quality manual include or make reference to supporting **procedures** including technical **procedures** and outline the structure of documentation used in the management system? ***Objective evidence is required**			

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4.2.6	Are the roles/responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with the International Standard, defined in the quality manual? ***Objective evidence is required**			
4.2.7	Does top management ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented?			
4.3	**Document Control**			
* 4.3.1	Does the laboratory establish and maintain **procedures** to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test/calibration methods, as well as drawings, software, specifications, instructions, and manuals? ***Objective evidence is required** *NOTE – This includes ANAB Accreditation Requirements.*			
4.3.2	**Document Approval & Issue**			
4.3.2.1	Are all documents issued to personnel in the lab as part of the management system reviewed and approved for use by authorized personnel prior to issue?			
* 4.3.2.1	Is a master list or an equivalent document control **procedure** identifying current revision status and distribution of documents in the management system established and readily available to			

17025 Element	Requirement	Customer Document Reference	Conformance C | NC | NA	Comments on Conformance
	preclude use of invalid and/or obsolete documents? ***Objective evidence is required**			
4.3.2.2	The **procedure** shall ensure:			
* a)	Does the **procedure** adopted ensure that authorized editions of appropriate documents are available at all locations where operations essential to effective functioning of the laboratory are performed?			
* b)	Does the **procedure** adopted ensure that documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements?			
* c)	Does the **procedure** adopted ensure that invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use?			
* d)	Does the **procedure** adopted ensure that obsolete documents retained for either legal or knowledge preservation purposes are suitably marked?			
4.3.2.3	Are management system documents generated by the lab uniquely identified and does such identification include the date of issue and/or revision identification, page numbering, total number of pages or a mark to signify the end of the document, and issuing authority(ies)?			
4.3.3	**Document Changes**			

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4.3.3.1	How are changes reviewed and approved by the same function? Does the designated person shall have access to background information?			
4.3.3.2	Is (where practicable) the altered or new text identified in the document or appropriate attachments?			
* 4.3.3.3	If the lab's documentation control system allows for amendment of documents by hand pending re-issue of documents, are **procedures** and authorities for such amendments defined and are amendments clearly marked, initialed, and dated? ***Objective evidence is required**			
* 4.3.3.4	Are **procedures** established to describe how changes in documents maintained in computerized systems are made and controlled? ***Objective evidence is required**			
4.4	**Review of requests, tenders and contracts**			
* 4.4.1	Does the laboratory establish and maintain **policies** and **procedures** for review of requests, tenders, and contracts? ***Objective evidence is required**			
* a)	Do the **policies** and **procedures** for these reviews leading to a contract for testing and/or calibration ensure that requirements, including methods to be used, are adequately defined, documented, and understood (see 5.4.2)?			

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* b)	Do the **policies** and **procedures** for these reviews leading to a contract for testing and/or calibration ensure that the laboratory has the capability and resources to meet the requirements?			
* c)	Do the **policies** and **procedures** for these reviews leading to a contract for testing and/or calibration ensure that the appropriate test and/or calibration method is selected and capable of meeting customers' requirements (see 5.4.2)?			
4.4.1	Are any differences between the request or tender and the contract resolved before any work commences? Is each contract acceptable to the laboratory and the customer?			
4.4.2	Are records of review, including any significant changes and maintained of pertinent discussions with a customer relating to the customer's requirements or results of the work during the period of execution of the contract? ***Objective evidence is required**			
4.4.3	Does the review also cover any work that is subcontracted by the lab?			
4.4.4	Is the customer informed of any deviation from the contract?			
* 4.4.5	If a contract needs to be amended after work has commenced, is the same contract review process repeated and are any amendments communicated to all affected personnel?			
4.5	**Subcontracting of Tests & Calibrations**			

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4.5.1	When a laboratory subcontracts work whether because of unforeseen reasons (e.g., workload, need for further expertise, or temporary incapacity) or on a continuing basis (e.g., through permanent subcontracting, agency, or franchising arrangements), is work placed with a competent subcontractor? A competent subcontractor is one that, for example, complies with the International Standard for the work in question. ***Objective evidence is required**			
4.5.2	Does the laboratory advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer (preferably in writing)? ***Objective evidence is required**			
4.5.3	Is the laboratory responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used?			
* 4.5.4	Does the laboratory maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of evidence of compliance with the International Standard for the work in question? ***Objective evidence is required**			
4.6	**Purchasing Services and Supplies**			
* 4.6.1	Does the laboratory have a **Policy** and **procedure** for the selection and purchasing of services and supplies it uses that affect the quality of tests and/or calibrations and do **procedures** exist for purchase, reception, and storage of reagents and laboratory consumable			

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17025 Element	Requirement	Customer Document Reference	Conformance C | NC | NA	Comments on Conformance
	materials relevant for tests and calibrations? ***Objective evidence is required**			
4.6.2	Have purchased supplies and reagents and consumables are inspected or otherwise verified prior to use. Records of such actions are recorded. ***Objective evidence is required**			
* 4.6.3	Do purchasing documents contain data describing the services and supplies ordered and be reviewed and approved for technical content prior to release? ***Objective evidence is required**			
4.6.4	Does the laboratory evaluate suppliers of critical consumables, supplies, and services which affect the quality of testing and calibration, and maintain records of these evaluations and a list of those approved? ***Objective evidence is required**			
4.7	**Service to the Client**			
4.7.1	Is the laboratory willing to cooperate with customers or their representatives in clarifying the customer's request to monitor the laboratory's performance in relation to work performed, provided the laboratory ensures confidentiality to other customers? ***Objective evidence is required**			
4.7.2	Does evidence exist that the laboratory encourages feedback, both positive and negative, from customers or other parties and how is feedback used to improve the management			

17025 Element	Requirement	Customer Document Reference	Conformance C | NC | NA	Comments on Conformance
	system, testing/calibration activities, and customer service?			
4.8	**Complaints**			
* 4.8	Does the laboratory have a **policy** and **procedure** for resolution of complaints received from customers or other parties? ***Objective evidence is required**			
4.8	Are records maintained of all complaints and of investigations and corrective actions taken by the laboratory? (see also 4.11) ***Objective evidence is required**			
4.9	**Control of Nonconforming Work**			
* 4.9.1	Does the laboratory have a **policy** and **procedures** that shall be implemented when any aspect of its testing/calibration work, or results of this work, do not conform to its own **procedures** or the agreed requirements of the customer? ***Objective evidence is required**			
* a)	Do the **policies**/**procedures** ensure that responsibilities and authorities for management of nonconforming work are designated and actions (including halting of work and withholding of test reports/calibration certificates, as necessary) are defined and taken when nonconforming work is discovered?			
* b)	Do the **policies**/**procedures** ensure that an evaluation of the significance of nonconforming work is made?			
* c)	Do the **policies**/**procedures** ensure that corrective actions are taken immediately,			

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17025 Element	Requirement	Customer Document Reference	Conformance C | NC | NA	Comments on Conformance
	together with any decision about the acceptability of nonconforming work?			
* d)	Do the **policies**/**procedures** ensure that, where necessary, the customer is notified and work is recalled?			
* e)	Do the **policies**/**procedures** ensure that the responsibility for authorizing resumption of work is defined?			
* 4.9.2	Where the evaluation indicates that nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own **policies** and **procedures**, are corrective action **procedures** given in 4.11 promptly followed? ***Objective evidence is required**			
4.10	**Improvement**			
4.10	Does the lab continually improve the effectiveness of its management system through the use of: the quality **policy**, quality objectives, audit results, analysis of data, corrective/preventive actions, management review?			
4.11	**Corrective Action**			
4.11.1	**General**			
* 4.11.1	Has the laboratory established a **policy** and a **procedure** and designated appropriate authorities for implementing corrective action when nonconforming work or departures from the **policies** and **procedures** in the management			

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	system or technical operations have been identified? ***Objective evidence is required**			
4.11.2	**Cause Analysis (CA)**			
* 4.11.2	Does the **procedure** for corrective action start with an investigation to determine the root cause(s) of the problem?			
4.11.3	**Selection and Implementation of Corrective Action.**			
4.11.3	Where corrective action is needed, does the laboratory identify potential corrective actions? Does it select and implement the action(s) most likely to eliminate the problem and to prevent recurrence?			
4.11.3	Are corrective actions to a degree appropriate to the magnitude and risk of the problem?			
4.11.3	Does the laboratory document and implement any required changes resulting from corrective action investigations? ***Objective evidence is required**			
4.11.4	**Monitoring of CA**			
4.11.4	Does the laboratory monitor the results to ensure that the corrective actions taken have been effective?			
4.11.5	**Additional Audits**			
* 4.11.5	Where identification of non-conformances or departures casts doubts on the laboratory's compliance with its own **policies** and **procedures** or on its compliance with the International Standard, does the lab ensure the			

17025 Element	Requirement	Customer Document Reference	Conformance C | NC | NA	Comments on Conformance
	appropriate areas of activity are audited in accordance with 4.14 as soon as possible?			
Effective implementation of Corrective Actions from previous assessment or surveillance, if applicable.				
4.12	**Preventive Action**			
4.12.1	Are needed improvements and potential sources of non-conformances, either technical or concerning the management system, identified?			
4.12.1	If preventive action is required, are action plans developed, implemented, and monitored to reduce the likelihood of occurrence of such non-conformances and to take advantage of opportunities for improvement?			
* 4.12.2	Do **procedures** for preventive actions include initiation of such actions and application of controls to ensure that they are effective? ***Objective evidence is required**			
4.13	**Control of Records**			
4.13.1	**General**			
* 4.13.1.1	Does the laboratory establish and maintain **procedures** for identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records? ***Objective evidence is required**			
4.13.1.1	Do quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions? ***Objective evidence is required**			

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4.13.1.2	Are all records legible and stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss?			
4.13.1.2	Are retention times of records established? ***Objective evidence is required**			
4.13.1.3	Are all records held secure and in confidence?			
4.13.1.4	Does the laboratory have **procedures** to protect/back-up records stored electronically and to prevent unauthorized access to or amendment of these records? ***Objective evidence is required**			
4.13.2	**Technical Records**			
4.13.2.1	Does the laboratory retain records of original observations, derived data, and sufficient information to establish an audit trail, calibration records, staff records, and a copy of each test report/calibration certificate issued, for a defined period? ***Objective evidence is required**			
4.13.2.1	Do records for each test/calibration contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test/calibration to be repeated under conditions as close as possible to the original? ***Objective evidence is required**			
4.13.2.1	Do records include the identity of personnel responsible for the performance of the sampling, test/calibration and checking of results? ***Objective evidence is required**			

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4.13.2.2	Are observations, data, and calculations recorded at the time they are made and identifiable to the specific task?			
4.13.2.3	Are mistakes single-line crossed out, correct entry made, and signed or initialed by person making correction? In the case of records stored electronically, are equivalent measures taken to avoid loss or change of original data?			
4.14	**Internal Audits**			
* 4.14.1	Does the lab periodically, and in accordance with a predetermined schedule and **procedure**, conduct internal audits of its activities to verify that its operations continue to comply with requirements of the management system and the International Standard? ***Objective evidence is required**			
4.14.1	Does the internal audit program address all elements of the management system, including the testing/calibration activities? It is the responsibility of the quality manager to plan/organize audits as required by the schedule and requested by management.			
4.14.1	Are such audits carried out by trained/qualified personnel who are, wherever resources permit, independent of the activity to be audited?			
4.14.2	If audit findings cast doubt on the effectiveness of operations or on the correctness or validity of the laboratory's test/calibration results, does the laboratory take timely corrective action and notify			

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	customers in writing if investigations show that the lab results may have been affected? ***Objective evidence is required**			
4.14.3	Are the areas of activity audited, the audit findings, and corrective actions that arise from them recorded?			
4.14.4	Do follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken? ***Objective evidence is required**			
4.15	**Management Review**			
* 4.15.1	In accordance with a predetermined schedule and **procedure**, does the laboratory's top management periodically conduct a review of the laboratory's management system and testing/calibration activities?			
4.15.1	Review shall include:			
4.15.1	Does the review ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements and does the review take account of the suitability of **policies** and **procedures**? ***Objective evidence is required**			
4.15.1	Does the review take account of reports from managerial and supervisory personnel? ***Objective evidence is required**			
4.15.1	Does the review take account of the outcome of recent internal audits? ***Objective evidence is required**			

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4.15.1	Does the review take account of corrective and preventive actions? ***Objective evidence is required**			
4.15.1	Does the review take account of assessments by external bodies? ***Objective evidence is required**			
4.15.1	Does the review take account of the results of inter-laboratory comparisons/ proficiency tests? ***Objective evidence is required**			
4.15.1	Does the review take account of changes in volume and type of work? ***Objective evidence is required**			
4.15.1	Does the review take account of customer feedback? ***Objective evidence is required**			
4.15.1	Does the review take account of complaints? ***Objective evidence is required**			
4.15.1	Does the review take account of reports from managerial and supervisory personnel? ***Objective evidence is required**			
4.15.1	Does the review take account of recommendations for improvement? ***Objective evidence is required**			
4.15.1	Does the review take account of other relevant factors, such as quality control activities, resources, and staff training? ***Objective evidence is required**			
4.15.2	Are findings from management reviews and actions that arise from them recorded and how does management ensure that those actions are carried out within an appropriate/agreed timescale? ***Objective evidence**			

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	is required			
5.0	**Technical Requirements**			
5.1	**General**			
5.1.1	Many factors determine correctness and reliability.			
5.1.2	Extent to which factors contribute to total uncertainty differs considerably between tests and calibrations.			
5.2	**Personnel**			
5.2.1	Ensure competence of all who operate equipment, perform test/calibrations (t/c), evaluate results & sign reports/certificates.			
5.2.2	Does management formulate goals with respect to the education, training, and skills of laboratory personnel?			
* 5.2.2	Does the laboratory have a **Policy** and **procedures** for identifying training needs and providing training of personnel? ***Objective evidence is required**			
5.2.2	Are training programs relevant to the present and anticipated tasks of the lab and how is the effectiveness of the training actions taken evaluated?			
5.2.3	Does the laboratory use personnel who are employed by, or under contract to the lab and where contracted and additional technical and key support personnel are used, does the laboratory ensure such personnel are supervised			

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	and competent and that they work in accordance with the laboratory's management system?			
* 5.2.4	Does the laboratory maintain current job descriptions for managerial, technical, and key support personnel involved in tests/calibrations? ***Objective evidence is required**			
5.2.5	Does management authorize specific personnel to perform particular types of sampling, tests/calibrations, to issue test reports/calibration certificates, to give opinions and interpretations, and to operate particular types of equipment? ***Objective evidence is required**			
5.2.5	Does the laboratory maintain records of relevant authorizations, competence, educational and professional qualifications, training, skills, and experience of all technical personnel, including contracted personnel and is this information readily available and does it include the date on which authorization and/or competence is confirmed? ***Objective evidence is required**			
5.3	**Accommodation & Environmental Conditions**			
5.3.1	Do laboratory facilities for testing/calibration (including but not limited to energy sources, lighting, and environmental conditions), facilitate correct performance of tests/calibrations?			
* 5.3.2	Does the laboratory monitor, control, and record environmental conditions as required by relevant specifications, methods, and **procedures** or where they influence the quality of the results? ***Objective evidence is required**			

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5.3.3	Is there effective separation between neighboring areas in which there are incompatible activities and are measures taken to prevent cross-contamination?			
5.3.4	Is access to and use of areas affecting the quality of the tests/calibrations controlled and does the lab determine the extent of control based on its particular circumstances?			
5.3.5	Are measures taken to ensure good housekeeping in the lab and are special **procedures** prepared where necessary? ***Objective evidence is required**			
5.4	**Test & Calibration Methods and Method Validation**			
5.4.1	**General**			
5.4.1	Does the laboratory use appropriate methods and **procedures** for all tests/calibrations within its scope? Do these include handling, transport, storage, and preparation of items to be tested or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test/calibration data?			
5.4.1	Does the laboratory have instructions on use and operation of all relevant equipment, and on handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests/calibrations? ***Objective evidence is required**			

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5.4.1	Are all instructions, standards, manuals, and reference data relevant to the work of the lab kept up to date and made readily available to personnel? (see 4.3)			
5.4.1	Do deviations from test/calibration methods occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer?			
5.4.2	**Selection of Methods**			
* 5.4.2	Does the laboratory use test/calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests/calibrations it undertakes?			
5.4.2	Are the preferred methods published in international, regional, or national standards used?			
5.4.2	Does the laboratory ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so?			
5.4.2	When necessary, is the standard supplemented with additional details to ensure consistent application?			
5.4.2	When the customer does not specify the method to be used, does the laboratory select appropriate methods that have been published either in international, regional, or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment? Lab-developed methods or methods adopted by the lab may also be used if			

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	they are appropriate for the intended use and if they are validated.			
5.4.3	**Laboratory-developed Methods**			
5.4.3	Is introduction of test/calibration methods developed by lab for its own use a planned activity and assigned to qualified personnel equipped with adequate resources?			
5.4.3	Are plans updated as development proceeds and is effective communication among all personnel involved ensured?			
5.4.4	**Non-standard Methods**			
5.4.4	When it is necessary to use methods not covered by standard methods, are these subject to agreement with the customer and do they include a clear specification of the customer's requirements and the purpose of the test/calibration and has the method developed validated appropriately before use?			
5.4.5	**Validation of Methods**			
5.4.5.1	Is the validation specific for intended use?			
5.4.5.2	Does the laboratory validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use?			
5.4.5.2	Is validation as extensive as is necessary to meet the needs of the given application or field of application?			

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5.4.5.2	Does the laboratory record the results obtained, the **procedure** used for the validation, and a statement as to whether the method is fit for the intended use? ***Objective evidence is required**			
5.4.5.3	The range and accuracy of the values obtainable from validated methods shall be relevant to the client's needs.			
5.4.6	**Estimate of Uncertainty of Measurement**			
* 5.4.6.1	Does the calibration laboratory or a testing laboratory performing its own calibrations, have and apply a **procedure** to estimate the uncertainty of measurement for all calibrations/types of calibrations? ***Objective evidence is required**			
5.4.6.2	Do testing labs have and apply **procedures** for estimating uncertainty of measurement? In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement.			
5.4.6.3	When estimating the uncertainty of measurement, are all uncertainty components which are of importance in the given situation taken into account using appropriate methods of analysis?			
5.4.7	**Control of Data**			
5.4.7.1	Are calculations and data transfers subject to appropriate checks in a systematic manner?			
* 5.4.7.2	When computers or automated equipment are used, the lab shall ensure that:			

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* a)	When computers or automated equipment are used for acquisition, processing, recording, reporting, storage, or retrieval of test/calibration data, does the laboratory ensure that computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use?			
* b)	Are **procedures** established and implemented for protecting the data and do such **procedures** include, at a minimum, integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing?			
c)	Are computers and automated equipment maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test/calibration data?			
5.5	**Equipment**			
* 5.5.1	Is the laboratory furnished with all items of measurement and test equipment required for the correct performance of the tests/calibrations (including sampling, preparation of test/calibration items and processing and analysis of test/calibration data)?			
5.5.1	In those cases, where the laboratory needs to use equipment outside its permanent control, does it ensure that the requirements of the International Standard are met?			
5.5.2	Is equipment/software used for testing, calibration, and sampling capable of achieving the accuracy required and does it comply with the			

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	specifications relevant to tests/calibrations concerned?			
5.5.2	Are calibration programs established for key quantities or values of the instruments where these properties have a significant effect on the results?			
5.5.2	Before being placed into service, is equipment (including that used for sampling) calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications? Is it checked or calibrated before use? (see 5.6)			
5.5.3	Is equipment operated by authorized personnel and are up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) readily available for use by the appropriate lab personnel?			
5.5.4	Is each item of equipment and its software used for testing/calibration and significant to the result, when practicable, uniquely identified?			
5.5.5	Records shall be maintained for each item of equipment, and shall include:			
a)	Do the records include at least the identity of the item of equipment and its software?			
b)	Do the records include at least the manufacturer's name, type identification, and serial number or other unique identification?			
c)	Do the records include at least the checks that equipment complies with specifications? (see 5.5.2)			

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d)	Do the records include at least the current location, where appropriate?			
e)	Do the records include at least the manufacturer's instructions, if available, or reference to their location?			
f)	Do the records include at least the dates, results, and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration?			
g)	Do the records include at least the maintenance plan, where appropriate, and maintenance carried out to date?			
h)	Do the records include at least the damage, malfunction, modification, or repair to the equipment?			
* 5.5.6	Does the laboratory have **procedures** for safe handling, transport, storage, use, and planned maintenance of measuring equipment to ensure proper functioning and to prevent contamination or deterioration? ***Objective evidence is required**			
5.5.7	Is equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, taken out of service?			
5.5.7	Does the laboratory examine the effect of the defect or departure from specified limits on previous tests/calibrations and institute the "Control of nonconforming work" **procedure**? (see 4.9).			

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5.5.8	Whenever practicable, is all equipment under the control of the lab and requiring calibration labeled, coded, or otherwise identified to indicate the status of calibration, including the date of the last calibration and the date or expiration criteria when re-calibration is due?			
5.5.9	When, for whatever reason, equipment goes outside the direct control of the laboratory, does the laboratory ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service?			
* 5.5.10	When intermediate checks are needed to maintain confidence in the calibration status of the equipment, are these checks carried out according to a defined **procedure**? ***Objective evidence is required**			
* 5.5.11	Where calibrations give rise to a set of correction factors, does the laboratory have **procedures** to ensure that copies (e.g., in computer software) are correctly updated? ***Objective evidence is required**			
5.5.12	Is test/calibration equipment, including both hardware and software, safeguarded from adjustments which would invalidate the test/calibration results?			
5.6	**Measurement Traceability**			
5.6.1	**General**			
5.6.1	Is all equipment used for test/calibrations, including equipment for subsidiary			

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	measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration, or sampling, calibrated before being put into service?			
* 5.6.1	Does the laboratory have an established program and **procedure** for the calibration of it equipment? ***Objective evidence is required**			
5.6.2	**Specific Requirements**			
5.6.2.1	**Calibration**			
5.6.2.1.1	Does the calibration laboratory's program for calibration ensure traceability to the International System of Units (SI)?			
5.6.2.1.1	Do the calibration certificates issued by these laboratories contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification? (See also 5.10.4.2). ***Objective evidence is required**			
5.6.2.1.2	There are certain calibrations that currently cannot be strictly made in SI units. In these cases, does the laboratory provide confidence in measurements by establishing traceability to appropriate measurement standards such as: • the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of material? • the use of specified methods and/or consensus standards that are clearly described and agreed to by all parties concerned? •			

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	participation in a suitable program of inter-laboratory comparisons where possible?			
5.6.2.2	**Testing**			
5.6.2.2.1	For testing laboratories, does the laboratory meet the requirements given in 5.6.2.1 for measuring/test equipment with measuring functions used unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result?			
5.6.2.2.1	When this situation arises, does the laboratory ensure that the equipment used can provide the uncertainty of measurement needed?			
5.6.2.2.2	When traceability of measurements to SI units is not possible and/or not relevant, does the laboratory meet the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards as required for calibration labs? (see 5.6.2.1.2).			
5.6.3	**Reference Standards & Reference Materials**			
5.6.3.1	**Reference Standards**			
* 5.6.3.1	Does the laboratory have a program and **procedure** for the calibration of its reference standards? ***Objective evidence is required**			
* 5.6.3.1	Are reference standards calibrated by a body that can provide traceability as described in 5.6.2.1? ***Objective evidence is required**			
5.6.3.1	Are such reference standards of measurement held by the lab used for calibration only and for no other purpose, unless it can be shown that			

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	their performance as reference standards would not be invalidated?			
5.6.3.1	Are reference standards calibrated before and after any adjustment?			
5.6.3.2	**Reference Materials**			
5.6.3.2	Are reference materials, where possible, traceable to SI units of measurement, or to certified reference materials?			
5.6.3.2	Are internal reference materials checked as far as is technically and economically practicable?			
5.6.3.3	**Intermediate Checks**			
* 5.6.3.3	Are checks needed to maintain confidence in the calibration status of reference, primary, transfer, or working standards and reference materials carried out according to defined **procedures** and schedules? ***Objective evidence is required**			
5.6.3.4	**Transportation and Storage**			
* 5.6.3.4	Does the laboratory have **procedures** for safe handling, transport, storage, and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity? ***Objective evidence is required**			
5.7	**Sampling**			
* 5.7.1	Does the lab have a sampling plan and **procedures** for sampling when it carries out			

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	sampling of substances, materials or products for subsequent testing/calibration?			
5.7.1	Sampling plan and **procedure** are available where sampling takes place.			
5.7.2	Where the customer requires deviations from, additions to, or exclusions from the documented sampling **procedure**, are these recorded in detail with the appropriate sampling data, included in all documents containing test/calibration results, and communicated to the appropriate personnel?			
* 5.7.3	Does the laboratory have **procedures** for recording relevant data and operations relating to sampling that forms part of the testing/calibration that is undertaken?			
5.8	**Handling of Test and Calibration Items**			
* 5.8.1	Does the laboratory have **procedures** for the transportation, receipt, handling, protection, storage, retention, and/or disposal of test/calibration items, including all provisions necessary to protect the integrity of the test/calibration item, and to protect the interests of the laboratory and the customer? ***Objective evidence is required**			
* 5.8.2	Does the laboratory have a system for identifying test/calibration items?			
5.8.3	Upon receipt of the test/calibration items, are abnormalities or departures from normal or specified conditions, as described in the test or calibration method, recorded? ***Objective evidence is required**			

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* 5.8.4	Does the laboratory have **procedures** and appropriate facilities for avoiding deterioration, loss, or damage to the test/calibration item during storage, handling, and preparation? ***Objective evidence is required**			
5.9	**Assuring the Quality of Test and Calibration Results**			
* 5.9.1	Does the laboratory have quality control **procedures** for monitoring the validity of tests/calibrations undertaken? ***Objective evidence is required**			
a)	Does the laboratory regularly use certified reference materials and/or internal quality control using secondary reference materials?			
b)	Does the laboratory participate in inter-laboratory comparison or proficiency-testing programs?			
c)	Is replicating tests/calibrations using the same or different methods?			
d)	Is the laboratory retesting or recalibration of retained items?			
e)	Is the laboratory correlating results for different characteristics of an item?			
5.9.2	Is quality control data analyzed and if the data analyzed is found outside pre-defined criteria, is planned action taken to correct the problem and to prevent incorrect results from being reported?			
5.10	**Reporting the Results**			

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5.10.1	**General**			
5.10.1	Are results of each test/calibration (or series of tests/calibrations carried out by the lab) reported accurately, clearly, unambiguously, objectively, and in accordance with any specific instructions in the test/calibration methods?			
* 5.10.1	Are the results reported, usually in a test report/calibration certificate, and do they include all theinformation requested by the customer and necessary for the interpretation of the test/calibration results and all information required by the method used? This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4. In case of tests/calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way.			
5.10.1	If any information listed in 5.10.2 to 5.10.4 is not reported to the customer, is it readily available in the laboratory which carried out the tests/calibrations?			
5.10.2	**Test Reports and Calibration Certificates**			
5.10.2	Test reports and calibration certificates include 17025 listed information, unless they have a valid reason for not doing so.			
a)	Unless the lab has valid reasons for not doing so, does each test report/calibration certificate include a title (e.g., “Test Report” or “Calibration Certificate”)?			

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b)	Unless the lab has valid reasons for not doing so, does each test report/calibration certificate include the name and address of the lab, and the location where the tests/calibrations were carried out, if different from the address of the lab?			
c)	Unless the lab has valid reasons for not doing so, does each test report/calibration certificate include unique identification of the test report/calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report/calibration certificate, and a clear identification of the end of the test report or calibration certificate?			
d)	Unless the lab has valid reasons for not doing so, does each test report/calibration certificate include the name and address of the customer?			
e)	Unless the lab has valid reasons for not doing so, does each test report/calibration certificate include identification of the method used?			
f)	Unless the lab has valid reasons for not doing so, does each test report/calibration certificate include a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated?			
g)	Unless the lab has valid reasons for not doing so, does each test report/calibration certificate include the date of receipt of the test/calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration?			

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h)	Unless the lab has valid reasons for not doing so, does each test report/calibration certificate include reference to the sampling plan and **procedures** used by the lab or other bodies where these are relevant to the validity or application of the results?			
i)	Unless the lab has valid reasons for not doing so, does each test report/calibration certificate include the test/calibration results with, where appropriate, the units of measurement?			
j)	Unless the lab has valid reasons for not doing so, does each test report/calibration certificate include the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate?			
k)	Where relevant, does the laboratory provide a statement that the results relate only to the items t/c?			
5.10.3	**Test Reports**			
5.10.3.1	Where necessary for the interpretation of results, the following shall be included in test reports:			
a)	In addition to the requirements listed in 5.10.2, do test reports, where necessary for the interpretation of the test results, include deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions?			
b)	Do test reports include, where relevant, a statement of compliance/non-compliance with requirements and/or specifications?			

Legend: *Lab Document Reference* = Laboratory document to demonstrate compliance. Include: Document Name(s), Paragraph Number(s) or Equivalent. *C* = Compliant, *NC* = Non-Compliant, *NA* = Not Applicable

* These requirements, at a minimum, will be covered during an AADR activity

17025 Element	Requirement	Customer Document Reference	Conformance C | NC | NA	Comments on Conformance
c)	Do test reports include, where applicable, a statement on the estimated uncertainty of measurement? Information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit.			
d)	Do test reports include, where appropriate and needed, opinions and interpretations (see 5.10.5)?			
e)	Do test reports include additional information which may be required by specific methods, customers, or groups of customers?			
5.10.3.2	Sampling in reports shall include:			
a)	Where necessary for the interpretation of test results, do test reports containing the results of sampling include the date of sampling?			
b)	Where necessary for the interpretation of test results, do test reports containing the results of sampling include an unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation, and serial numbers as appropriate)?			

17025 Element	Requirement	Customer Document Reference	Conformance C | NC | NA	Comments on Conformance
c)	Where necessary for the interpretation of test results, do test reports containing the results of sampling include the location of sampling, including any diagrams, sketches or photographs?			
d)	Where necessary for the interpretation of test results, do test reports containing the results of sampling include a reference to the sampling plan and **procedures** used?			
e)	Where necessary for the interpretation of test results, do test reports containing the results of sampling include details of any environmental conditions during sampling that may affect the interpretation of the test results?			
f)	Where necessary for the interpretation of test results, do test reports containing the results of sampling include any standard or other specification for the sampling method or **procedure**, and deviations, additions to or exclusions from the specification concerned?			
5.10.4	**Calibration Certificates**			
5.10.4.1	Calibration certificates shall also include:			
a)	Where necessary for the interpretation of calibration results, do calibration certificates include the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results?			

Legend: *Lab Document Reference* = Laboratory document to demonstrate compliance. Include: Document Name(s), Paragraph Number(s) or Equivalent. *C* = Compliant, *NC* = Non-Compliant, *NA* = Not Applicable

* These requirements, at a minimum, will be covered during an AADR activity

17025 Element	Requirement	Customer Document Reference	Conformance C | NC | NA	Comments on Conformance
b)	Where necessary for the interpretation of calibration results, do calibration certificates include the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof?			
c)	Where necessary for the interpretation of calibration results, do calibration certificates include evidence that the measurements are traceable? (see note in 5.6.2.1.1)			
5.10.4.2	Does the calibration certificate relate only to quantities and results of functional tests?			
5.10.4.2	When a statement of compliance is made omitting the results and associated uncertainties, the does the laboratory record those results and maintain them for future reference?			
5.10.4.2	When a statement of compliance is made, does the laboratory take uncertainty into consideration?			
5.10.4.3	When an instrument for calibration has been adjusted or repaired, are the calibration results before and after adjustment or repair (if available) reported?			
5.10.4.4	Does the laboratory ensure its calibration certificate (or calibration label) contains no recommendation on the calibration interval except where this has been agreed with the customer? This requirement may be superseded by legal regulations.			

Legend: *Lab Document Reference* = Laboratory document to demonstrate compliance. Include: Document Name(s), Paragraph Number(s) or Equivalent. *C* = Compliant, *NC* = Non-Compliant, *NA* = Not Applicable

* These requirements, at a minimum, will be covered during an AADR activity

17025 Element	Requirement	Customer Document Reference	Conformance C | NC | NA	Comments on Conformance
5.10.5	**Opinions and Interpretations**			
5.10.5	When opinions and interpretations are included, does the laboratory document the basis upon which the opinions and interpretations have been made and Are opinions and interpretations clearly marked as such in a test report?			
5.10.6	**Testing and Calibration Results Obtained from Subcontractors**			
5.10.6	When the test report contains results of tests performed by subcontractors, are these results clearly identified? Does the subcontractor report the results in writing or electronically?			
5.10.6	When a calibration has been subcontracted, does the laboratory performing the work issue the calibration certificate to the contracting lab?			
5.10.7	**Electronic Transmission of Results**			
5.10.7	In the case of transmission of test/calibration results by telephone, telex, facsimile, or other electronic or electromagnetic means, are the requirements of the International Standard met? (see also 5.4.7).			
5.10.8	**Format of Reports and Certificates**			
5.10.8	Is the format designed to accommodate each type of test/calibration carried out and to minimize the possibility of misunderstanding or misuse?			
5.10.9	**Amendments to Reports or Certificates**			

Legend: *Lab Document Reference* = Laboratory document to demonstrate compliance. Include: Document Name(s), Paragraph Number(s) or Equivalent. *C* = Compliant, *NC* = Non-Compliant, *NA* = Not Applicable

* These requirements, at a minimum, will be covered during an AADR activity

17025 Element	Requirement	Customer Document Reference	Conformance C | NC | NA	Comments on Conformance
5.10.9	Are material amendments to a test report/calibration certificate after issue made only in the form of a further document, or data transfer, which includes the statement: "Supplement to Test Report (or Calibration Certificate), serial number...(or as otherwise identified)", or an equivalent form of wording?			
5.10.9	Do such amendments meet all requirements of the International Standard?			
5.10.9	When it is necessary to issue a complete new test report or calibration certificate, is it uniquely identified and does it contain a reference to the original that it replaces?			

ANAB Accreditation Requirements

Document Number	Document Name	Customer Document Reference	Conformance C | NC | NA	Comments on Compliance
*** Accreditation Requirements for Calibration Laboratories** ➢ Proficiency Testing ➢ Traceability ➢ Traceability using RM's ➢ Uncertainty of Measurement ➢ In House Calibrations				

Legend: *Lab Document Reference* = Laboratory document to demonstrate compliance. Include: Document Name(s), Paragraph Number(s) or Equivalent. *C* = Compliant, *NC* = Non-Compliant, *NA* = Not Applicable

* These requirements, at a minimum, will be covered during an AADR activity

Document Number	Document Name	Customer Document Reference	Conformance C | NC | NA	Comments on Compliance
*** Accreditation Requirements for Testing Laboratories** ➢ Proficiency Testing ➢ Traceability ➢ Traceability using RM's ➢ Uncertainty of Measurement ➢ In House Calibrations				
*** Accreditation Requirements for Control and Use of Accreditation Symbol** ➢ Verify appropriate use on reports and certificates. ➢ Verify appropriate use on marketing materials. ➢ Verify appropriate use on website ➢ Verify use of combined symbol with ILAC mark if used ➢ Confirm calibration stickers requirements				
Scope of Accreditation & associated uncertainty budgets. Assure appropriate uncertainties are complete and note if changed.				
Areas of Concern				

Legend: *Lab Document Reference* = Laboratory document to demonstrate compliance. Include: Document Name(s), Paragraph Number(s) or Equivalent. *C* = Compliant, *NC* = Non-Compliant, *NA* = Not Applicable

* These requirements, at a minimum, will be covered during an AADR activity

Federal Communications Commission
Office of Engineering and Technology
Laboratory Division

February 29, 2016

ACCREDITED TESTING LABORATORY
FCC TECHNICAL ASSESSMENT CHECKLIST

The following checklist identifies specific items to be evaluated during the technical assessment of a testing laboratory to determine the capability and competence of that laboratory to perform testing to show compliance with FCC equipment authorization requirements under the FCC Rules and Regulations contained in Title 47 of the Code of Federal Regulations (47 CFR). This checklist is intended to serve as a guide, and it provides a minimum list of items to be included in the technical evaluation of the test laboratory as part of a complete ISO/IEC 17025 assessment. This checklist is not intended to replace good engineering judgment of the technical assessor(s), or a thorough evaluation of the facility. As such, other related items not shown in this checklist may be evaluated and documented by the assessor(s). The accreditation body shall attest that all responses in this checklist are complete and accurate. The completed checklist for each laboratory is submitted to the FCC, and is made publicly available.

Basic requirements for measurement procedures for unintentional and intentional radiators are listed in 47 CFR § 15.31. A list of measurement procedures is also found on the FCC equipment authorization measurements page at: https://www.fcc.gov/oet/ea/eameasurements.html. Finally, the FCC Knowledge Database provides additional guidance on testing devices subject to the FCC's rules.

A testing laboratory is not required to be assessed to all of the standards identified in this checklist, but for the testing laboratory to be recognized by the FCC they must be assessed and compliant with all applicable parts of each standard for which FCC recognition is being requested. In cases where the FCC doesn't recognize all portions of a standard or different versions of a standard contain conflicting requirements, any deviations from full compliance with a standard [*e.g.*, site validation for radiated emissions measurements above 1 GHz per ANSI C63.4-2014 5.5.1 a) vs. ANSI C63.10-2013 5.2] should be noted in this checklist and by the accreditation body.

A testing laboratory is not required to be assessed and recognized for all of the scopes identified in KDB Publication 974614 but the FCC will not recognize partial scopes and in order for a scope to be recognized by the FCC an accredited testing laboratory must be capable of performing all testing covered within the scope. The FCC does allow an accredited testing laboratory to meet the full scope requirements using multiple testing locations of the same company at different locations within the same country.

The Equipment Authorization Report and Order FCC 14-208 has updated the incorporation-by-reference of the measurement procedures for unintentional radiators (ANSI C63.4-2014) and intentional radiators (ANSI C63.10-2013). These new standards may be used effective immediately. A one-year transition period is provided in the rules, which requires that these standards must be used for all part 15 device compliance testing on or after July 13, 2016. During the transition period, the new editions as well as the older editions of ANSI C63.4 and ANSI C63.10 (as described in FCC Public Notice DA 09-2478) may be used.

When the procedures in ANSI C63.4-2014 or ANSI C63.10-2013 are used for radiated emission measurements, the test site used shall meet the following site validation requirements:

- As of the effective date of the rules (July 13, 2015), test facilities used to make radiated emission measurements from 30 MHz to 1 GHz are required to meet the site validation requirements in ANSI C63.4-2014.
- For radiated emissions in 1 GHz to 40 GHz, a test facility can use either of the two site validation options in 5.5 of ANSI C63.4-2014. After the transition date of July 13, 2018, each test facility is required to comply with the site validation requirements in CISPR 16-1-4:2010-04.

Validation of the test site acceptability criterion shall be confirmed no less than once every three years.

The version of each measurement procedure covered during the assessment shall be recorded under the scope of accreditation on the checklist.

The assessor(s) shall mark in the checklist all items observed and verified at the laboratory. Mark the letter "Y," representing "yes," to show conformance with the criteria. **Mark the letter "N," representing "No," to show a deficiency.** If the item is “Not Applicable,” mark “N/A.” As necessary, explanations of any deficiency, exception, or comments shall be recorded in the space provided.

Accredited Testing Laboratory
FCC Technical Assessment Checklist

Laboratory Name	
Laboratory Contact	
Accreditation Body	
Date of Assessment	
Completed by (Assessor name(s))	
Scope of Accreditation (Indicate standards covered by assessment: *e.g.*, ANSI C63.4-2014, ANSI C63.10-2013, and FCC MP-5.)	
Type of Assessment	
Date Checklist Completed	

I. SCOPE OF ASSESSMENT *(The laboratory shall possess or demonstrate access to appropriate FCC Rules, standards, and measurement methods, consistent with their scope of accreditation. Has the test laboratory been assessed and found to be capable and competent to perform testing to the standards listed below?)*

Y	N	N/A	1. ANSI C63.4-2003: *American National Standard for Method of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz.*	
Y	N	N/A	2. ANSI C63.4-2009: *American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz.*	
Y	N	N/A	3. ANSI C63.4-2014, *American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz.*	
Y	N	N/A	4. ANSI C63.10-2009, *American National Standard for Testing Unlicensed Wireless Devices.*	
Y	N	N/A	5. ANSI C63.10-2013, *American National Standard for Testing Unlicensed Wireless Devices.*	
Y	N	N/A	6. Is the testing laboratory familiar with KDB Publications 789033 and 905462, and capable of testing devices subject to all Unlicensed National Information Infrastructure policy and rule requirements?	

Y	N	N/A	7. ANSI C63.17-2013, *American National Standard Methods of Measurement of the Electromagnetic and Operational Compatibility of Unlicensed Personal Communications Services (UPCS) Devices.*	
Y	N	N/A	8. ANSI C63.19-2007, *American National Standard for Methods of Measurement of Compatibility Between Wireless Communication Devices and Hearing Aids.*	
Y	N	N/A	9. ANSI C63.19-2011, *American National Standard for Methods of Measurement of Compatibility Between Wireless Communication Devices and Hearing Aids.*	
Y	N	N/A	10. Is the testing laboratory familiar with KDB Publication 285076 and capable of testing devices subject to Hearing Aid Compatibility (HAC) requirements for mobile handsets?	
Y	N	N/A	11. ANSI/TIA-603-D-2010, *Land Mobile FM or PM Communications Equipment Measurement and Performance Standards.*	
Y	N	N/A	12. Is the testing laboratory familiar with KDB Publication 971168 and capable of testing wideband devices operating in Commercial Mobile (Radio) Services?	
Y	N	N/A	13. RF exposure KDB publications, in conjunction with the fundamental SAR concepts in IEEE Std 1528-2013, *IEEE Recommended Practice for Determining the Peak Spatial-Average Specific Absorption Rate (SAR) in the Human Head from Wireless Communications Devices: Measurement Techniques.* KDB publication requirements take precedence over any variations in IEEE Std 1528-2013.	
Y	N	N/A	14. Is the testing laboratory familiar with KDB Publications 447498 and 865664 and capable of testing devices subject to general RF exposure guidance and SAR measurement guidance, respectively?	
Y	N	N/A	15. FCC MP-5-1986: *Methods of measurement of radio noise emissions from Industrial, Scientific and Medical (ISM) equipment*.	
Y	N	N/A	16. Does the testing laboratory *possess or can demonstrate access* to all FCC Rules and Regulations (47 CFR) and standards for the scope of the assessment?	
Y	N	N/A	17. Are the measurement antennas properly calibrated in accordance with ANSI C63.5-2006?	

Y	N	N/A	18. Is any measurement software used by the testing laboratory documented in the test report?	
Y	N	N/A	19. For each type and size of EUT to be measured, does each radiated emission test facility comply with the conditions and requirements of the appropriate test procedure?	
Y	N	N/A	20. Are LISN(s), filters, and isolation transformers, if used, properly installed? Is the LISN bonded to the ground reference plane?	
Y	N	N/A	21. Does the radiated emission test site(s) meet the site validation requirements of 5.4 of ANSI C63.4-2014 for the frequency range of 30 MHz to 1 GHz?	
Y	N	N/A	22. Does the radiated emission test site(s) meet the site validation requirements of 5.5 of ANSI C63.4-2014 for the frequency range of 1 GHz 40 GHz?	
Y	N	N/A	23. Does the radiated emission test site(s) meet the site validation requirements of CISPR 16-1-4:2010-04 for the frequency range of 1 GHz 40 GHz?	
Y	N	N/A	24. Was the test site validation for performing radiated emissions measurements completed in the last three years?	
Y	N	N/A	25. Does the EMI receiver or spectrum analyzer cover the required frequency range per the scope of accreditation for the measurements to be performed by the testing laboratory? (47 CFR § 15.33)	
Y	N	N/A	26. Does the test laboratory have an up to date description of measurement facilities as required by 47 CFR § 2.948?	
Y	N	N/A	27. Is the testing laboratory familiar with KDB Publication 935210 and capable of testing devices subject to signal booster requirements?	
II. EMISSION TESTS				
Y	N	N/A	28. Are the AC power-line conducted emission tests performed in accordance with the applicable parts of ANSI C63.4-2014 and 47 CFR §§ 15.31-15.35 and 15.107?	
Y	N	N/A	29. Are the guidelines in ANSI C63.4 and FCC MP-5 followed for large EUTs, including *in-situ* measurements, if appropriate?	

Y	N	N/A	30. Is the conducted emission test setup in accordance with ANSI C63.4 with the required separation between the EUT and any conducting surfaces maintained?	
Y	N	N/A	31. Is the EUT connected to one LISN and all the peripherals connected to one or more LISNs or a power strip to one LISN; i.e., per ANSI C63.4-2014?	
Y	N	N/A	32. For each type of EUT, are measurements made over the correct frequency ranges and the correct detectors and bandwidth as required by 47 CFR §§ 15.33, 15.35, and 18.309?	
Y	N	N/A	33. Are the radiated emission tests performed in accordance with the proper standard?	
Y	N	N/A	34. Were radiated emission tests observed, and is the radiated emission test setup in accordance with proper standard?	
Y	N	N/A	35. Are unintentional radiators, other than ITE, tested in accordance with the requirements in 47 CFR § 15.31 and the procedures in the appropriate standard?	
Y	N	N/A	36. Are intentional radiators tested in accordance with the requirements in 47 CFR § 15.31 and the procedures in the appropriate standard?	
Y	N	N/A	37. Does the radiated emission measurement represent the maximized cable configuration and worst case mode of EUT operation?	
Y	N	N/A	38. For each type of EUT, are the correct frequency ranges investigated and the correct measurement detectors and bandwidth used per 47 CFR §§ 15.33 and 15.35?	
Y	N	N/A	39. If the laboratory has a TEM waveguide, are the requirements followed in making radiated emission measurements using TEM waveguides? (ANSI C63.4, KDB Publication 823311)	
III. TEST REPORTS (*Assessor should request to review several sample test reports for various types of products.)*				
Y	N	N/A	40. Have several sample test reports for various types of products been reviewed for accuracy?	
Y	N	N/A	41. Does each of the test reports contain all the required information, and does the laboratory follow the report disposition procedure?	
Y	N	N/A	42. Does the test report reference the standard used and specify any deviations?	

Y	N	N/A	43. Is the rationale for selecting and arranging the EUT clearly stated, and are the components of the EUT system clearly identified?	
Y	N	N/A	44. Does the test report include photographs or detailed sketches of the EUT configuration?	
Y	N	N/A	45. Does the measurement report include a sample calculation with all conversion and correction factors used?	
Y	N	N/A	46. Does the testing laboratory use external resources/subcontractors to perform testing, and if so do they have procedures in place to ensure that the external resources are properly accredited and FCC recognized?	
Y	N	N/A	47. If external resources/subcontractors are used to perform testing, do the test reports clearly identify the work performed by the external resources/subcontractors and the results of the testing?	
IV. PERSONNEL COMPETENCY *(The following is a list of general or lead-in questions, which are intended to be used as a guide to assess competency of laboratory personnel. Additional specific questions should be used to determine the technical competency of the personnel performing the measurement.)*				
Y	N	N/A	48. Are laboratory personnel able to obtain recent FCC Rules and appropriate KDB guidance?	
Y	N	N/A	49. Has each laboratory personnel responsible for testing been able to demonstrate performing a measurement of an applicable device?	
Y	N	N/A	50. Do the test personnel know how to determine if an emission is from the EUT or is an ambient signal? Do the test personnel know how to handle an emission that is close to, or coincident with, an ambient signal?	
Y	N	N/A	51. Can the test personnel explain the FCC requirements for testing a product in accordance with the requirements in 47 CFR §§ 15.31 to 15.35? Are the test personnel knowledgeable of the FCC testing conditions for different types of products?	

Y	N	N/A	52. Arrange for one of the laboratory personnel, at each type of site, replicate at least three frequency points on the horizontal site attenuation, and at least three frequency points on the vertical site attenuation. Is the test performed correctly, and is the site attenuation data at these frequencies consistent with the previously recorded data? *Note: Select frequencies from previous data that have both low and high deviations from the NSA.*	
Y	N	N/A	53. For equipment requiring RF exposure evaluation (SAR and MPE), are the test personnel knowledgeable of the test reduction, test exclusion, and measurement, or if applicable, numerical simulation procedures and requirements in KDB Publications?	
Y	N	N/A	54. For measurements of equipment requiring Hearing Aid Compatibility (HAC) testing, are the test personnel knowledgeable of the test setup and procedures?	

Change Notice

07/31/2015: 853844 D01 Accredited Lab Checklist v02 replaces 853844 D01 Accredited Lab Checklist v01. The checklist was updated to reflect changes related to FCC 14-208.

02/29/2016: 853844 D01 Accredited Lab Checklist v02r01 replaces 853844 D01 Accredited Lab Checklist v02. The checklist was updated to reflect changes related to partial scopes of accreditation and the addition of a separate scope for signal boosters.

Technical Competence Evaluation (OPIEF)

FM 2804	Authority: Accreditation Manager	Effective: 2017/02/24

Assessor Report Technical Competence Evaluation	**Customer / Location:**	**Assessment dates:**

Parameter/ Test Name or Technology	Depth of Assessment*	Names of Personnel Interviewed	Environment / Accom	Standards/ Equipment/ Ref. Materials	Procedure/ Operating Instructions	Measurement Uncertainty Verification	Traceability; Verification/ Calibration	Sampling; Handling/ Preparation	Quality Checks	Records	Report/ Certificate

Technical Competency Evaluation Observations:

Parameter/ Test Name or Technology	Depth of Assessment*	Names of Personnel Interviewed	Environment / Accom	Standards/ Equipment/ Ref. Materials	Procedure/ Operating Instructions	Measurement Uncertainty Verification	Traceability; Verification/ Calibration	Sampling; Handling/ Preparation	Quality Checks	Records	Report/ Certificate

Technical Competency Evaluation Observations:

Parameter/ Test Name or Technology	Depth of Assessment*	Names of Personnel Interviewed	Environment / Accom	Standards/ Equipment/ Ref. Materials	Procedure/ Operating Instructions	Measurement Uncertainty Verification	Traceability; Verification/ Calibration	Sampling; Handling/ Preparation	Quality Checks	Records	Report/ Certificate

Technical Competency Evaluation Observations:

Parameter/ Test Name or Technology	Depth of Assessment*	Names of Personnel Interviewed	Environment / Accom	Standards/ Equipment/ Ref. Materials	Procedure/ Operating Instructions	Measurement Uncertainty Verification	Traceability; Verification/ Calibration	Sampling; Handling/ Preparation	Quality Checks	Records	Report/ Certificate

Technical Competency Evaluation Observations:

Parameter/ Test Name or Technology	Depth of Assessment*	Names of Personnel Interviewed	Environment / Accom	Standards/ Equipment/ Ref. Materials	Procedure/ Operating Instructions	Measurement Uncertainty Verification	Traceability; Verification/ Calibration	Sampling; Handling/ Preparation	Quality Checks	Records	Report/ Certificate
Technical Competency Evaluation Observations:											

Parameter/ Test Name or Technology	Depth of Assessment*	Names of Personnel Interviewed	Environment / Accom	Standards/ Equipment/ Ref. Materials	Procedure/ Operating Instructions	Measurement Uncertainty Verification	Traceability; Verification/ Calibration	Sampling; Handling/ Preparation	Quality Checks	Records	Report/ Certificate
Technical Competency Evaluation Observations:											

Date completed:	**Assessor:**
Notes:	

***O = Observed Test; P = Procedure Reviewed; I = Interviewed Personnel; E = Equipment Inspected; F = Field (On-Site); IC = Internal Calibration; NR = Not Running**

Instructions for Completing Scope/Method Assessment Review

Complete table for each parameter/test/technology and the corresponding methods in the following categories:

- Parameter, Test Name or Technology: For calibration labs, list parameter and tool (dimensional-calipers, force, etc.); for testing labs list test category and name (Chemical, Biological, etc.) and GC-MS or Salmonella
- Depth of Assessment: Record the extent to which the parameter/test was assessed as follows, noting there may be a combination (e.g., O/I/P, I/P, etc.):
  O = Observed Calibration or Test
  I = Interviewed Personnel
  P = Procedure Reviewed
  E = Equipment Inspected
  F = Field (On-Site) Calibration and/or Test
  IC = Internal Calibration
  NR = Not Running

You must verify at a minimum that the lab has the equipment, method, and trained personnel to perform each calibration/test on the proposed scope.

- Personnel Interviewed: List names of personnel with prospective competence for the method.
- Environmental Conditions: Indicate whether the environment/facility/equipment was suitable for the methods listed, and any environmental monitoring devices (which may also require traceability).
- Standards/Equipment//Reference Materials: All reference standards and equipment used, listing all mentioned on the proposed scope of accreditation.
- Procedure/Operating Instructions: Indicate specific laboratory internal procedures or instructions for performing the calibration or test, and whether they were acceptable. Be sure to note the same methods as indicated on the proposed scope.
- Measurement Uncertainty: Indicate whether uncertainty analysis is required for the method; if required, indicate if laboratory analysis is acceptable (may indicate to be verified later as TBV).
- Verification/Calibration: Indicate whether the calibration or verification data for the relevant equipment is acceptable, and any objective evidence observed.
- Sampling; Handling/Preparation of Items: Indicate all protective gear used for the methods, whether the laboratory performs any sampling for the listed methods, and indicate if those activities and any handling or preparation performed are acceptable.
- Quality Checks: Indicate quality checks in place and whether they are acceptable.
- Records: Indicate whether the appropriate records are maintained for the listed methods and what records were reviewed. Note all hand-written logbooks, or forms used. Many may have differing record retention times.
- Report/Certificate: Indicate whether the results for the listed methods are appropriately reported in accordance with ISO/IEC17025 and any requirements of the methods. Note if reports issue out of a database, electronic, or templates.
- Document observations of technical competency evaluations by stating the witnessed testing/calibrations and presenting information that would define the observed technical competencies of the personnel witnessed and / or interviewed during the Method Witness. (See “Example”).

Example

Assessor Report Method Review Matrix			Customer / Location: Carl's Cal Shop Fort Wayne, IN						Assessment dates: July 8, 2015		
Parameter/ Test Name or Technology	**Depth of Assessment***	**Names of Personnel Interviewed**	**Environment / Accomo**	**Standards/ Equipment/ Ref. Materials**	**Procedure/ Operating Instructions**	**Measurement Uncertainty Verification**	**Traceability; Verification/ Calibration**	**Sampling; Handling/ Preparation**	**Quality Checks**	**Records**	**Report/ Certificate**
Floor scale (5000 lb x 0.1 lb)	OPIEF	John Doe	76 °F at customers	Class F weights	NIST Handbook 44 2015	Updated 2/28/15	Cert #12345678	SOP 8 rev 1 4/21/15	Performed 2x a year	Worksheet FM 1234	CERT #56789
Technical Competency Evaluation Observations: **John was qualified to perform the calibration on 1/14/14, training matrix present. Environment is monitored at the customer's facility with Temp gauge #12234 which was calibrated by Joe's Cal House certificate number 4556. Joe's Cal House is accredited by ANAB certificate number AC-0007. Class F weights used for the calibration were from Kit 123 serial numbers; 12, 23, 34, 45, 56, 100, 101. The weights were calibrated by the State Weights and Measures division. The calibration was performed to the requirements of 2015 version of NIST Handbook 44 Section 2.20. The uncertainty budget was developed by John Doe accounting for the significant contributors for the calibration of a floor scale. The weights were transported by a covered truck preventing rain, sleet or snow to prevent deterioration. Intermediate checks are performed twice a year according to WI 990 and results are records on FM 1234. The calibration certificate provided accounts for all the necessary requirements of the standard, ANAB and the customer.**											